PROSPECTIVE RANDOMIZED CONTROL STUDY ON EFFECT OF ADDING DEXMEDETOMIDINE TO CAUDAL BUPIVACAINE FOR POSTOPERATIVE ANALGESIA IN CHILDREN

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CERTIFICATE

This is to certify that the dissertation entitled, **"PROSPECTIVE RANDOMIZED CONTROL STUDY ON EFFECT OF ADDING DEXMEDETOMIDINE TO CAUDAL BUPIVACAINE FOR POSTOPERATIVE ANALGESIA IN CHILDREN",** Submitted by Dr. N. HARIPRAKASH in partial fulfilment for the award of the degree of Doctor of Medicine in Anaesthesiology by the Tamilnadu Dr. M.G.R. Medical University, Chennai is a bonafide record of the work done by him in the INSTITUTE OF ANAESTHESIOLOGY & CRITICAL CARE, Madras Medical College, during the academic year 2011-2013.

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DECLARATION

I, **Dr. N. HARIPRAKASH** solemnly declare that this dissertation entitled **"PROSPECTIVE RANDOMIZED CONTROL STUDY ON EFFECT OF ADDING DEXMEDETOMIDINE TO CAUDAL BUPIVACAINE FOR POSTOPERATIVE ANALGESIA IN CHILDREN"** is a bonafide work done by me in the Institute of Anaesthesiology & critical care, Madras Medical College and Rajiv Gandhi Government General hospital, Chennai, during the period 2010-2013 under the able guidance of **Prof. *M. VASANTHI, MD., DA., DNB.,*** Director, Institute of anaesthesiology & critical care, Madras Medical College and Rajiv Gandhi Government General Hospital, Chennai – 3 and submitted to **The Tamilnadu Dr. MGR Medical University,** Guindy, Chennai – 32, in the partial fulfillment of the requirements for the award of the degree of MD Anaesthesiology (Branch X).

Place:

Date:

(Dr. N. HARIPRAKASH)

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CONTENTS

INTRODUCTION

The word pain is derived from greek word ***poena,*** meaning penalty .It is defined as an unpleasant sensory or emotional experience associated with actual or potential damage or described in terms of such damage

But this definition is critiqued because nonverbal or preverbal individuals and those who are cognitively impaired may be unable to describe their pain.[1]

Early assumptions that neonate and young children are less able to respond to pain and stress has been refuted and stress response in particular has been well characterized. The developmental neurobiology of pain is complex and changes in pain processing takes place in early life.

Mechanism of acute pain includes both peripheral and central components of the response to noxious stimulation of injury. In the periphery ,injury induces a local inflammatory response which includes sensitization of nociceptors and primary hyperalgesia .High threshold A and C fibres conduct noxious inputs to CNS, initiating a chain of events which includes reflex withdrawl from the stimulus, aversive behaviour, and perception of pain. Sustained 'C' fibre inputs

provoke a number of changes, known as central sensitization, which alter spinal sensory processing, leading to hyperalgesia and allodynia at the site of injury.

These mechanisms are different in early life.

1. Clear measurable responses to pain which can be reduced by analgesia have been observed at all ages including the newborn but these are important differences in these responses. Sensory thresholds are lower in neonate and reflex response more exaggerated. The motor component of the withdrawl reflex is less coordinated and tends to involve whole body movements. In addition, the receptive fields of sensory neurons are relatively larger and more overlapping than in adults which probably influences sensory discrimination and localization.
2. Evidence for nerve plasticity and “windup” or sensitization after prolonged painful stimulation also exists at all ages. In adults, CNS stimulation following noxious occur as a result of sustained C fibre inputs. Both A delta fibre and C fibres rather than C fibres the number, mediated in early life.
3. The number, location distribution and functionality of many important receptors and N methyl D aspartate(NMDA) receptor, which is important for central sensitization.

4. The peripheral inflammatory response is not fully matured at birth and also undergoes developmental regulation.

Pain measurement[2,3,4]

The vast range of physiological and behavioural responses, cognitive abilities, psychological development between the preterm neonate and adolescent poses enormous problems for valid and reliable pain measurement.

Methods of pain assessment

1) Self report measures: faces, Manchester, VAS pain scales

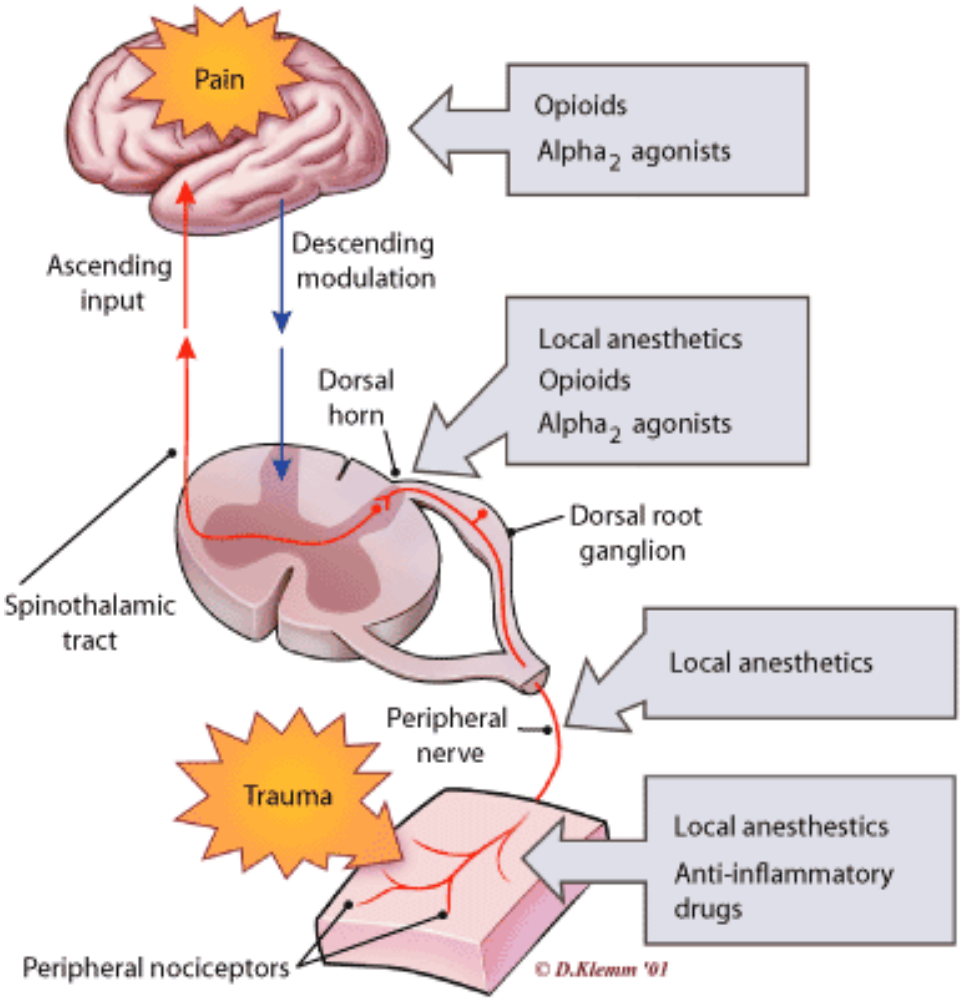
2) ***Observational behavioural measures:*** e.g., CHEOPS, FLACC. COMFORT SCALE

FLACC behavioural pain scale: total score0_10

criiteria	**Score 0**	**Score 1**	**Score 2**
Face	No particular expression or smile	Occasional grimace or frown, withdrawn, uninterested	Frequent to constant quivering chin, clenched jaw
Legs	Normal position or relaxed	Uneasy, restless, tense	Kicking, or legs drawn up
Activity	Lying quietly, normal position, moves easily	Squirming, shifting back and forth, tense	Arched, rigid or jerking
Cry	No cry (awake or asleep)	Moans or whimpers; occasional complaint	Crying steadily, screams or sobs, frequent complaints
Consolability	Content, relaxed	Reassured by occasional touching, hugging or being talked to, distractible	Difficult to console or comfort

Given the complexity of the pain mechanism, effective treatment of pain requires the use of multimodal therapies that target multiple sites along pain pathways.

Pain can be treated at the peripheral level using local anaesthetics, NSAIDs[5,6] ,or opioids. At the spinal cord level it can be treated with local anaesthetics, opioids. At the spinal cord level it can be treated with local anaesthetics, opioids, alpha $_2$ agonists, and cortical level opioids can be used. Most cases of ***moderate to severe pain are best treated with a combination of analgesic techniques***

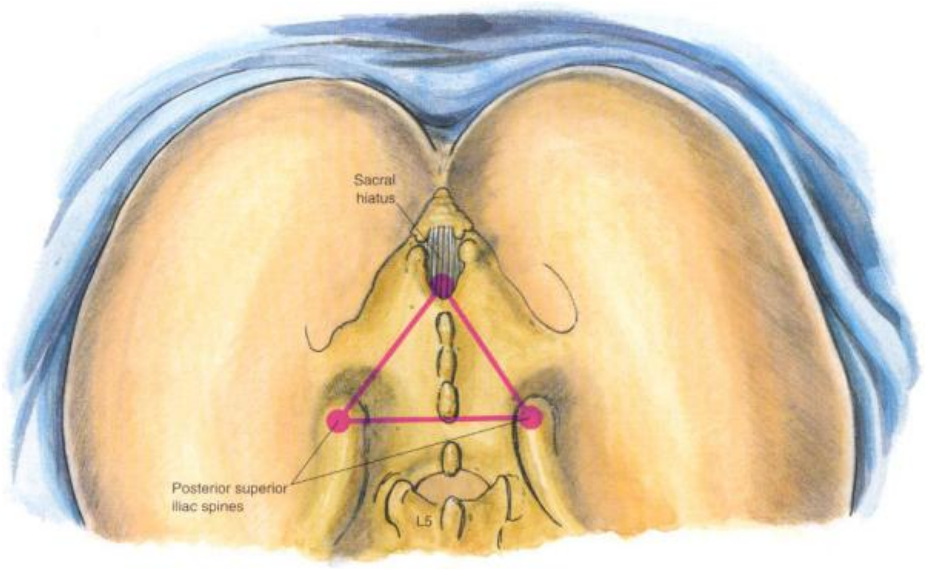


AIM OF STUDY

This study compares the efficacy and safety of using caudal epidural administration of dexmedetomidine 1 µg/kg with 0.25% bupivacaine vs 0.25% bupivacaine for providing postoperative pain relief in children undergoing lower abdominal surgeries.

ANATOMY OF CAUDAL SPACE[7,8,9]

Caudal anaesthesia is the oldest and still the most commonly used technique of epidural blockade in children. It is performed via the sacral hiatus, through the sacrococcygeal membrane. Posterior superior iliac spines and sacral hiatus forms equilateral triangle.

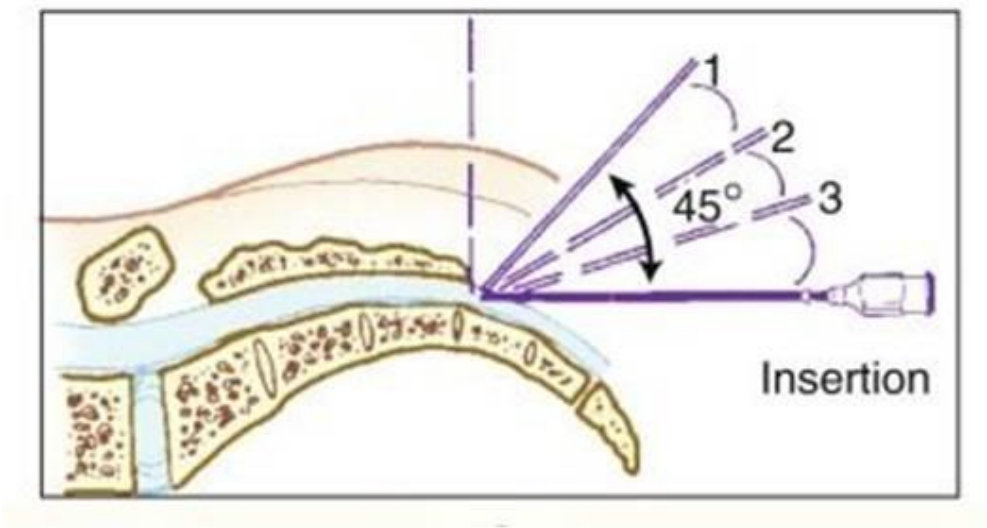


It is a V-shaped aperture resulting from the lack of dorsal fusion of fourth and fifth sacral vertebral arches. It is limited laterally by two palpable bony structures, the ***sacral cornua*** and it is covered by ***sacrococcygeal membrane*** (sacral continuation of ligamentum flava). The distance from skin to epidural space hardly influenced by age and

weight of the patient, 25 mm long needles are long enough to reach the sacral epidural space and short enough to prevent inadvertent dural puncture in most patients. With growth, the axis of sacrum changes and sacral hiatus may even close. These changes make the caudal epidural anaesthesia more difficult to perform in children older than 6 to7 years of age

Technique of caudal block[10]

As in the preparation for any major regional anaesthesia technique, all equipment must be assembled, checked, including block tray, resuscitation equipment and suction.



The needle used for this procedure will depend on clinical circumstances. For single injection caudal block in a child, 2-3 cm disposable 23 to 25 G needle should be used. The needles should be

short bevelled because they give better feel when different tissues are penetrated and they have lesser tendency to form barbs if bone is struck. The bevel is more likely to enter the canal if it is very shallow. If catheter is planned a short 5 to 7 cm 18G Crawford tip needle and standard epidural catheter is recommended.

The use of tuohy needle to insert a catheter is not recommended. The needle tip will lie in the long axis of the canal, and Tuohy tip there will direct the catheter toward the wall rather than the axis of the canal, as with a Crawford or IV needle.

Positioning:[10]

1. The preferred position is lateral sim's position. Left side down for right handed person with the lower leg slightly flexed at the

hip and upper leg more flexed such that it lies over and above the lower leg and also in contact with bed .This manoeuvre tends to separate the buttocks.

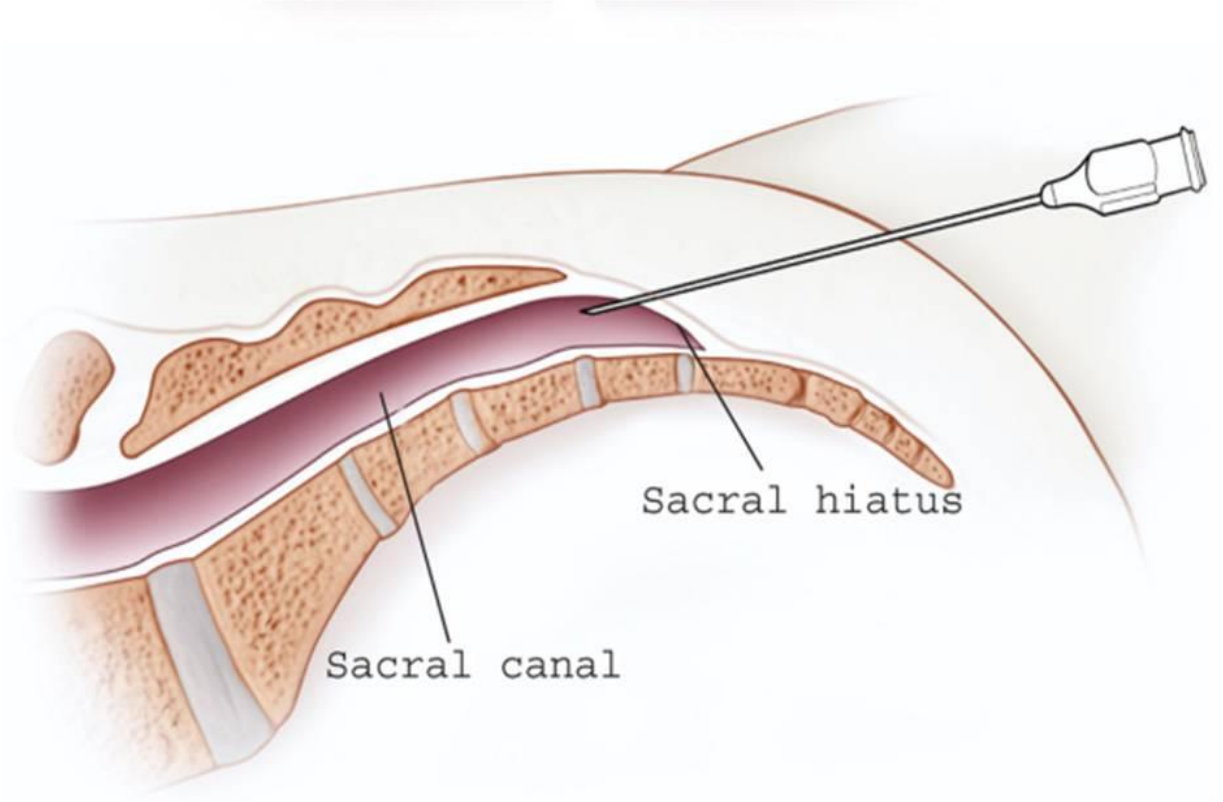
2. Prone position with pillow under the pelvis. Both legs are rotated so that the toes of both feet are facing medially. This again separates the buttocks
3. Knee chest position still may be useful, particularly for pregnant patients.

Confirmation of bony landmarks is the key to successful block. In the thin young patients protrusions of sacral cornua can be seen without palpation, and the shallow depression over the sacral hiatus can be seen between them.

Having found the area of suspected hiatus, it is well to keep the palpating hand in position until after the needle insertion because landmarks can be easily obscured especially in obese patients. Because the canal has tendency to become deeper as one progresses cephalad, the canal entry is facilitated if a point of needle is chosen toward the upper end of hiatus. The intial angle of needle insertion is 120^0 to the back. Penetration of sacrococcygeal ligament has a characteristic feel to it. This ‘pop’ can be learned only by practice.

There is feeling of emptiness after penetration of ligament in most cases until the anterior wall is contacted. This contact should not be sought. The needle, both hub and shank should then be depressed toward the skin to align the needle approximately in the long axis of the canal. It may then be inserted further a centimeter. After aspiration ,a test dose of local anaesthetic drug is injected at this point.

SIGNS OF CORRECT NEEDLE PLACEMENT[10]



- The presence of sacral bone on each side does not exclude the possibility of entry into a decoy hiatus.
- The lack of CSF, air, blood on aspiration is important.
- There should be no subcutaneous bulge or superficial crepitus after injection of 2 to 3 ml of anaesthetic solution or air
- There should be no tissue resistance to injection
- When correctly positioned needle should be able to move in the canal
- There should be no local pain during injection
- Paresthesia or feeling of fullness that extends from sacrum to the soles of the feet is common during injection but ceases on completion.
- A useful test when substantial doubts about the needle position cannot be resolved is to inject 2 to 4 ml of air while listening with ear or stethoscope over lumbar vertebra
- If catheter is inserted ,it should enter the canal freely with same or greater ease than in lumbar region

COMPLICATIONS

- Epidural haematoma
- Epidural abscess
- Dural puncture
- Intravenous placement
- Intraosseous placement

POSTOPERATIVE PROBLEMS

- Periosteal hematoma and pain.
- Urinary retention
- Infection
- Neurological complications

Indications and contraindications:

Caudal epidural anaesthesia is indicated for infra-umbilical surgical procedures, including inguinal hernia repair, urinary and lower digestive tract surgery, and orthopaedic procedures on pelvic girdle and lower extremities.

Contraindicated in ***major malformations*** of sacrum ***, meningitis*** and ***intracranial hypertension***.

Selection of drug

The drug dose required for epidural blockade at a given dermatomal level depends on the ***volume*** (not concentration***) of the local anaesthetic*** and the ***volume of epidural space,*** which may change with age. The formula of ***takasaki*** and colleagues has best approximated good clinical result is ***Volume (ml)=0.05mlkg /dermatome to be blocked***

Caudal epidural anaesthesia is basically a single shot technique. The dosage of ***armitage***[11] remains the most dependable.

0.5 ml /kg all sacral dermatomes are blocked,

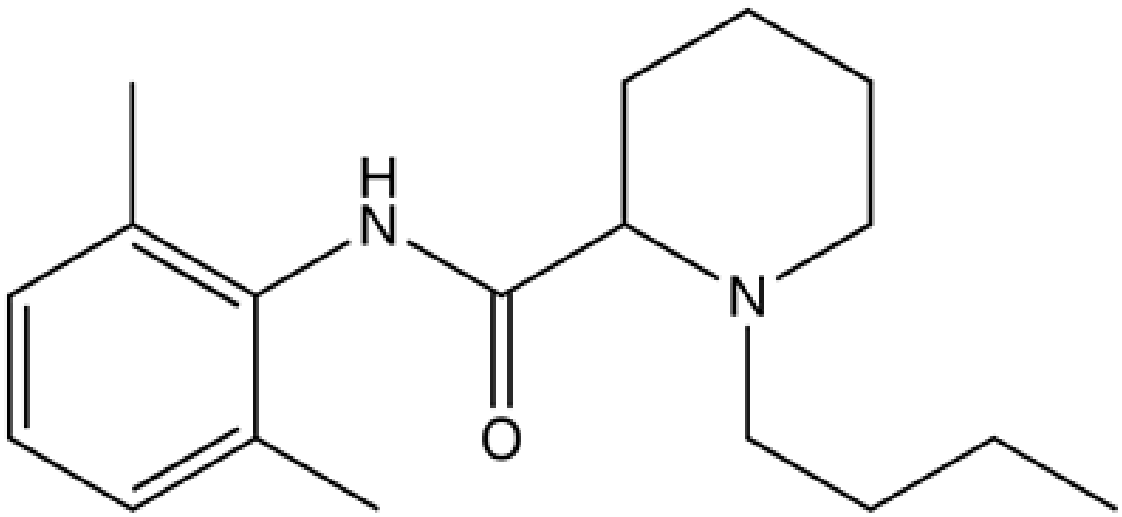
1ml/kg sacral and lumbar dermatomes are blocked,

At 1.25 ml/kg there is a danger of excessive rostral spread (aboveT4)[12]

PHARMACOLOGY OF BUPIVACAINE[13]

Bupivacaine is an amide local anaesthetic agent. It belongs to the homologous series of n-alkyl substituted pipecholyl xylidines. It was first synthesized by **Ekenstam** in 1957 and was used clinically in 1963. It is produced for clinical use as a racemic mixture containing both 'S' and 'R' forms in equal proportion. It is supplied as a hydrochloride salt.

CHEMICAL STRUCTURE:



1-butyl-n-(2,6-dimethyl phenyl) -2-piperidine decarboxamide hydrochloride monohydrate.

PHYSIO-CHEMICAL PROFILE[11]:

Molecular weight	-	288
pKa	-	8.1
Plasma protein binding	-	95%
Partition coefficient	-	28 (lipid solubility)
T ½	-	210 min
Clearance	-	8.3 l/min

MECHANISM OF ACTION:

Like all the other local anaesthetics, it inhibits Na channels. It decreases or prevents large transient increase in permeability of the cell membranes to Na ions that follows depolarization of the membrane and thereby blocks the nerve conduction. It also reduces the permeability of the resting nerve membrane to potassium ions as well as sodium ions and hence has got a stabilising action on all excitable membranes.

EFFECTS:

- Local – nerve blockade
- Regional – pain, temperature, touch, motor power and vasomotor tone supplied by the nerves are blocked.
- Systemic – effects due to systemic absorption or accidental intravenous administration.

It is 4 times more potent than lignocaine but the onset of action is slower. The duration of action is longer. Sensory block is more marked than the motor block.

SYSTEMIC EFFECTS:

CNS:

Can produce

- Circumoral numbness, metallic taste
- Tinnitus, light headedness, dizziness
- Confusion, slurred speech
- convulsions

CVS:

- depresses automaticity and contractility of the heart
- slows conduction of cardiac action potential as it causes prolongation of PR and QR intervals on ECG.
- Re-entrant phenomenon and ventricular arrhythmias
- Results mostly from high lipid solubility
- R-enantiomer is more toxic than S-enantiomer
- Pregnancy increases cardiotoxic effects of bupivacaine

KINETICS:

- Rapidly absorbed from the site of injection
- Peak systemic concentration – 5 to 30 minutes after administration
- Duration of action – 360 to 720 minutes
- Metabolism in liver – dealkylation to pipecoloxylidine, aromatic hydroxylation
- Excretion – 5% by kidney as unchanged drug and rest as metabolites

PREPARATION:

- 0.25%, 0.5% solutions in 10, 20 ml vials, respectively
- 5mg/ml (0.5%) bupivacaine with 80 mg dextrose (to increase baricity) in 4 ml ampoules for subarachnoid injection (baricity – 1.0207)

USES:

- Central neuraxial blocks
- For local infiltration subcutaneously
- Peripheral nerve blockade

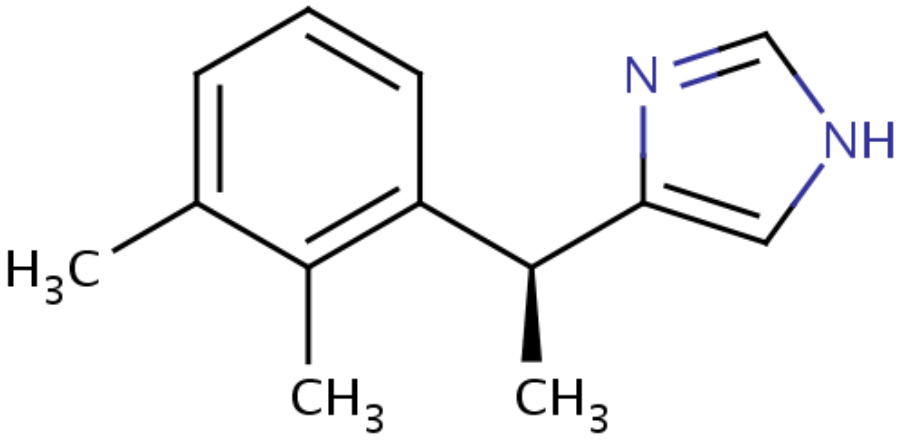
CONTRAINDICATIONS:

- Known hypersensitivity to amide local anaesthetics
- Intravenous regional anaesthesia(IVRA)

MAXIMAL DOSE:

2.5 mg/kg body weight and the strength used is 0.25 – 0.75% with or without adrenaline (1:200000 or 1:400000)[11]. Adrenaline does not prolong its effect, but reduces its toxicity

PHARMACOLOGY OF DEXMEDETOMIDINE[14]



Dexmedetomidine is the d-enanatiomer of medetomidine which was a drug initially used in veterinary medicine for sedation and analgesia. It was introduced into clinical practice in 1999 and was approved by FDA for sedation of mechanically ventilated patients for less than 24 hours

It belongs to the imidazole subclass of α2 receptor agonists, similar to clonidine. α2 agonists provide sedation, anxiolysis, analgesia, hypnosis and centrally mediated sympatholysis. The initial

idea behind the use of dexmedetomidine was due to observations made in patients receiving clonidine therapy.

Clonidine therapy has been found to decrease the MAC value of halothane when used along with dexmedetomidine.

Dexmedetomidine is a very selective α2 agonist with a high ratio of specificity for α2 when compared to α1(1600>1), when compared to clonidine (200>1).

METABOLISM AND PHARMACOKINETICS

After administration, dexmedetomidine is rapidly redistributed and is extensively metabolised in the liver by undergoing conjugation, n-methylation or hydroxylation and is excreted in the urine and faeces.

Dexmedetomidine is largely protein bound (94%). Since dexmedetomidine has such profound effects on the cardiovascular system, large doses may alter its own pharmacokinetics. With large doses, due to marked vasoconstriction, the drug's volume of distribution is decreased. The drug displays non linear pharmacokinetics. These pharmacokinetics are unaltered by age, weight or renal failure, but it is a function of height.

The elimination half life is 2-3hours with a context sensitive half time of 4 minutes after a 10 minute infusion to 250 minutes after an 8 hour infusion.

PHARMACOLOGY

It is a nonselective α2 agonist. Three subtypes of α2 receptors have been described in humans α2a, α2b and α2c. The α2a receptors are located in the periphery and the α2b and α2c receptors are located in the brain and spinal cord. These receptors are membrane spanning G proteins and stimulation causes inhibition of adenylate cyclase and modulation of ion channels.

Post synaptic α2 receptors cause vasoconstriction, whereas presynaptic α2 receptors inhibit the release of norepinephrine and attenuate the effect of vasoconstriction. The overall effects of stimulation of α2 receptors causes sedation and analgesia, sympatholysis.

Stimulation of α2a receptors-

- Presynaptic inhibition of norepinephrine release
- Analgesia
- Sedation
- Hypotension

- Inhibition of epileptic seizures

Stimulation of α2b receptors-

- Hypertension
- Placental angiogenesis
- Hypertensive effect of etomidate
- Analgesic effect of nitrous oxide

Stimulation of α2c receptors-

- Feedback inhibition of adrenal catecholamine release
- Analgesic effect of moxonidine
- Modulation of behaviour

EFFECTS ON CNS

SEDATION

They produce a sedative hypnotic effect by action on the locus coeruleus and an analgesic effect by action on the locus coeruleus and the spinal cord. It produces a decrease in the activity of the projections of locus coeruleus to the ventrolateral preoptic nucleus. This increases GABA and galanin release in the tuberomammillary nucleus which then produces a decrease in histamine release in the cortical and

subcortical projections. These agonists inhibit ion conductance through L type or P type calcium channels and facilitates conductance through calcium activated potassium channels.

Patients sedated with dexmedetomidine are easily arousable and will usually follow commands and cooperate even while being tracheally intubated. If left undisturbed, these patients fall asleep easily. The sleep induced by dexmedetomine is very similar to physiological non-rapid eye movement (NREM)sleep. There is limited respiratory depression and this drug provides a wide safety margin.

Since it is approved for use only for short term sedation(less than 24 hour), chances of addiction, dependence or tolerance does not seem to be a problem

Other uses of dexmedetomidine include-

- Addiction treatment
- Use in rapid detoxification of opioid
- Cocaine withdrawal syndrome
- Iatrogenically induced Benzodiazepine and opioid tolerance after prolonged sedation

ANALGESIA

α2 agonists have an analgesic effect when injected in the intrathecal or epidural route. When injected intrathecally they help with cancer pain, neuropathic pain and other kinds of short term pain.

When dexmedetomidine is injected into the epidural space it rapidly diffuses into the intrathecal space, studies showed that 22% of the drug was found in the CSF. A fall in the blood pressure is seen within 5-20 minutes of administration. The primary site of analgesic action is deemed to be the spinal cord.

Intrathecal or epidural administration of dexmedetomidine decreases the narcotic requirements by 50%.

Dexmedetomine has not been found to be useful in attenuating heat pain or electrical pain. The analgesic effect of dexmedetomine has been compared to remifentanil. Therefore when used in a clinical situation where pain is likely to occur, it is efficacious to use dexmedetomine in addition to a narcotic agent.

OTHER CNS EFFECTS

Dexmedetomine reduces intracerebral catecholamine outflow and thus results in less neural damage following injury. It modulates

apoptotic and anti apoptotic proteins and decreases the release of the excitatory neurotransmitter glutamate.

Dexmedetomine also reduces muscle rigidity after high dose opioid administration. It also increases growth hormone secretion in a dose dependent manner but does not affect the other pituitary hormones.

RESPIRATORY SYSTEM EFFECTS

Dexmedetomine administered in concentrations for sedation reduces minute ventilation, but the response to increasing carbondioxide is retained. At the highest concentrations, Paco2 increased by 20% and respiratory rate increased with increasing concentrations from 14 breaths/min to 25 breaths/min. Dexmedetomine also has hypercarbic arousal phenomenon which has been described during normal sleep as a protective phenomenon.

CARDIOVASCULAR SYSTEM EFFECTS

It causes a decreased heart rate, decreased systemic vascular resistance; indirectly decreases myocardial contractility,cardiac output and systemic blood pressure. A bolus dose of dexmedetomine usually causes a biphasic response . An initial increase in blood pressure and a decrease in heart rate occurs from the baseline which is probably due

to the vasoconstrictive effects when stimulating α2 receptors. Heart rate returned to baseline and blood pressure gradually declined to 15% below baseline by one hour.

It causes a compensated reduction in systemic sympathetic tone without changes in baroreflex sensitivity. It also blunts the heart rate and systemic sympathetic activation owing to sweating.

The perioperative use of α2 agonists reduces the incidence of perioperative myocardial ischaemia.

USES

As a pre medicant was 0.33 to 0.67ug/kg given 15 minutes before surgery. It reduces thiopental requirements by 30% and decreases the volatile requirement by 25% and attenuates the haemodynamic response to endotracheal intubation when compared with 2ug/kg of fentanyl.

It can be used for maintenance of anaesthesia with propofol or desflurane plus dexmedetomidine wtih a 0.5-0.8ug/kg bolus and a 0.4ug/kg/hr infusion. It improves haemodynamics compared with desflurane-fentanyl or propofol-fentanyl anaesthetics.

It is used a sedative at a dose of 0.2 to 0.7ug/kg/hr. It has also been used a sedative for patients with narcotic induced respiratory depression or sleep apnoea

ALPHA 2 ANTAGONIST:

Atipamezole:

Scheinin *et al.* reported about the ability of atipamezole, a novel selective α2-adrenoceptor antagonist, to reverse the sedative properties of of intramuscular dexmedetomidine were dose-dependently antagonized by intravenous atipamezole. However, the sensitivity for reversal of these two responses may be different. Because the agonist and the antagonist have similar elimination half-lives, the likelihood of recurrence of the clinical effects of dexmedetomidine after reversal by atipamezole is small. Therefore the a2 agonists provide a titratable form of hypnotic sedation that can be reversed readily.

REVIEW OF LITERATURE

Hennawy et al, 2007[15]

They did a study on 60 patients undergoing vesicourethral reflux surgery allocated into three group as A,B, C. After induction of general anaesthesia with oxygen and sevoflurane and, intubation was done. After putting patient in lateral position group A received 1ml /kg of caudal bupivacaine 0.25% with dexmedetomidine 2µ/kg making volume of 1ml,group B received 1ml /kg of 0.25%bupivacaine and clonidine 2µ/kg making volume of 1ml, group C received caudal bupivacaine 0.25% with 1ml of normal saline. Premedication like atropine was not given in this study. No other sedatives. Analgesics, antiemetics was given intra operatively. End tidal sevoflurane concentraton, analgesia time, FLACC score, sedation score was monitored for first 24 hours. Hypotension requiring IV fluid boluses and bradycardia needed atropine also noted perioperatively. Duration of analgesia in group A was 16 hours with confidence interval of 95%,in group B analgesic time was 12hours, in group C analgesic time was 5 hours(p value<0.001). All group of patients experienced no significant haemodynamic changes. No significant difference was noted between clonidine and dexmedetomine regarding analgesic

time. Morphine 0.1mg/kg was given as rescue analgesia if FLACC score more than 4.

Vijay G anand et al.,[16]

They compared the effect of adding dexmedetomine to caudal ropivacaine for postoperative analgesia in chidren undergoing lower abdominal surgeries in children. They selected 60 paediatric patients undergoing lower abdominal surgeries and allocated into two groups.group R received 1ml /kg of 0.25% ropivacaine with 0.5 ml of normal saline group RD received 1 ml/kg of 0.25% ropivacaine with 1 microgram/kg of dexmedetomidine making volume to 0.5ml after induction of general anaesthesia by 50%:50% oxygen and nitrous oxide with sevoflurane 8% in spontaneous ventilation. Duration of analgesia was assessed by FLACC score, sedation by ramsay sedation score, emergence time from anaesthesia was noticed. Intra operatively HR, NIBP, SPO2 was monitored every 5 minutes then postoperatively for every 4 hours. Bradycardia was considered HR 80/min in children less than 1 year, less than 60/min between 1 to 6 years. Hypotension was defined systolic blood pressure 70 plus (2x age in years) with altered tissue perfusion. Duration of analgesia was 5.5 in group R compared to 14.5 hours in group RD .Sedation score also more in

group RD. No significant hemodynamic changes occurs in introp and postoperatively. Adverse effects like bradycardia, hypotension, urinary retention, PONV, respiratory depression (SPO2 less than 95%) also statistically not significant in between these two groups. Syp.Paracetamol 15mg /kg was given as rescue analgesic if FLACC SCORE more than 4.

Saadawy et al.,[17]

It was the first study to compare the effect of adding dexmedetomine to caudal bupivacaine for postoperative analgesia in children between the ages of 1to 6 years undergoing infraumbilical surgeries. It was prospective, randomised, double blinded study. 60 patients randomly allocated into two groups (n=30). Patients are induced with Inj, Propofol 3-4 mg/kg and appropriate size LMA was inserted. BIS, NIBP, HR, SPO2, ETCO2 was monitored intra operatively. BIS was maintained around40-60 during intraop period by adjusting sevoflurane concentration. Inadequate analgesia was considered increase in HR, BP more than 15% from baseline value. Hypotension and bradycardia was defined decrease in HR, BP more than 30% from baseline values. dexmedetomine group received 1µ/kg with bupivacaine 0.25% 1ml/kg, bupivacaine group received iml/kg of

0.25% bupivacaine. Sedation score, objective pain scale, emergence score was noted postoperatively. Mean duration of sedation in dexmedetomine group was 210±72mins compared to bupivacaine group 24±72mins (p value<0.05). Maximal decrease in BP was noted between 25-30 minutes in dexmedetomidine group. Maximal decrease in HR was31±5 in group B compared to38±8 in group BD. maximal decrease in HR was noted in 39±7 mins in group BD compared to28±7 minutes in group B. One patient went for bradycardia required atropine. Hypopotension was treated with vasopressors or fluid boluses. They conclude that caudal dexmedetomidine provide prolonged analgesia with arousable sedation.

Mausumi neogi et al.,2010.,

They conducted randomised, control,double blinded study on 75 patients undergoing elective inguinal herniotomy allocated into rhree groups. All patients received oral midazolam 0.5 mg/kg as premedicant 30 minutes before surgery. Anaesthesia was induced with oxygen with incremental concentration of halothane. Entotracheal intubation was after paralysing patient with 0.5mg /kg of Inj.atacurium. Anaesthesia was maintained with oxygen and nitrous oxide 40%:60% with 0.5%halothane. NIBP, HR, SPO2 was monitored

intra operative and postoperative period. Duration of analgesia was assessed by CRIES scale. Analgesic time in group R was6.32 ± 0.46hours (median, confidence interval 95%), group C was 13.17 ± 0.68 hours, group D was15.26±0.86hours. Sedation score in first hour in all three group was maximum of 2, in six hours it was 3, in 12 hours it was 4 according to 4 point scale.no significant haemodynamic difference was noted in all three groups in first 24 hours.adverse effects like respiratory depression, bradycardia, hypotension, pruritus, post operative nausea and vomiting also statiscally not significant in all 3 groups.

Xiang Q et al.,2012 november[18]

They conducted a study on sixty patients undergoing hernia sac ligation assigned into two groups for addition of dexmedetomine to caudal bupivacaine for inhibing tractional pain. All patients premedicated with oral midalazolam 0.5mg/kg one hour prior to surgery. Anaesthesia was induced with ketamine intravenous injection. Standard monitoring like SPO2. HR, NIBP was used. Traction pain was considered if increase in HR, NIBP more than 20% from baseline value. Ketamine rescue analgesia was given if patient feels pain. Post operatively Inj. Fentanyl was given as rescue

analgesia. In group B they received 0.25% bupivacaine 1ml/kg, in group BD they received 0.25% bupivacaine 1ml/kg with 1µ/kg dexmedetomine. First fentanyl injection was given after 860 minutes in group BD compared to 320 minutes in group B. Amount of fentanyl injection needed in group BD was 2.5µ(1.2) compard to 6.9µ(1.6). They concluded that group BD needed lesser doses of fentanyl compared to group B. In BD group one patient needed ketamine rescue analgesia compared to 13 patients needed IV ketamine rescue analgesia in group B.

Mostafa el hamamsy et al.,[19]

They conducted a study on 112 patients undergoing surgical procedure lasting more than 90 minutes to test the efficacy of adding additives to single shot caudal to prolong postop analgesia and reduce the dose of rescue analgesia. They received1ml /kg of equal mixture of 0.25%bupivacaine and lignocaine 1% with dexmedetomine 1.5µ/kg in group D, 1ml/kg of local anaesthetic mixtures with clonidine 2µ/kg in group C,1ml/kg of local anaesthetic tramadol 2µ/kg in group T,1ml/kg of local anaesthetic with fentanyl 2µ/kg in group F after induction of general anaesthesia with halothane and oxygen with 60%nitrous oxide. Anaesthesia was maintained isoflurane 0.6% with oxygen and

nitrous oxide. The study was conducted was conducted in ASA I –II patients weighing 10-30kg, between 3 to 10 years of age. 12 patients were excluded from study because of surgical procedure lasting less than 90 minutes and failed caudal. HR, BP, SPO2 was monitored for first 6 hours. Inadequate analgesia was considered increase in HR or BP more than 15% from baseline. Hypotension and bradycardia was defined if HR or BP decreaing more than 20% from baseline. Pain was assessed by objective pain scale, if more than 11 rectal paracetamol 15mg/kg was given. Sedation score was assessed by subjective sedation scale. They concluded mean duration of analgesia in group B was 245±10 mins,in group D 347±10 minutes. In group C 350±10 mins, in group T 280 mins, in group F 280 minutes. Clonidine and dexmedetomine group provide significant postoperative analgesia than tramadol and fentanyl group. But clonidine and dexmedetomine group there is no statiscally significant postoperative duration of analgesia.7 patients in clonidine group 5 patients in dexmedetomineetomine group required atropine to bradycardia. It was statiscally significant.

Rajni Gupta et al [20], compared intrathecal dexmedetomidine and fentanyl as adjuvants to Bupivacaine in 60 patients undergoing lower abdominal surgeries, they were allocated into 2 groups and received

either 12.5mg hyperbaric bupivacaine + 5µg dexmedetomidine (group D) . 12.5 mg Hyperbaric bupivacaine + 25µg of fentanyl (group F) . They observed that patient in group D had longer sensory and motor blockade and reduced demand for rescue analgesia for 24 hours.

Sukwinder Kaur Bajua et al,[21] did a comparative evaluation of epidural dexmedetomidine and clonidine in patients undergoing vaginal hysterectomies.50 patients undergoing vaginal hsytrectomies were randomly allocated in 2 groups : RD and RC.

RD - Ropivacaine (17 ml of 0.75%) + dexmedetomidine(1.5 µg/kg)

RC- Ropivacaine (17 ml of 0.75%) + Clonidine (2 µg/kg)

Onset of analgesia, sensory and motor blockade, sedation level , duration of analgesia and adverse effects were compared. Demographic profile, initial and post operative block variables and cardio pulmonary parameters were comparable non significant in both groups. whereas sedation was better in RD group and incidence of side effects was less in RD group.

Ansermino et al.,[22]

They conducted study for evaluating the efficacy of adding non opioid drugs like clonidine, midazolam, ketamine to local anaesthetics for prolonged duration of analgesia. Also they concluded that non opioid drugs effectively prolongs duration of analgesia. However neurotoxicity of the drugs cannot be excluded.

Parmeswari et al.,[23]

They conducted a prospective, randomized control study on 100 children aged 1 to 3 years posted for infra umbilical surgeries for testing the efficacy of α agonist like clonidine to bupivacaine forpost operative analgesia in children.

Group A received one ml per kg of 0.25% buoivacaine .

Group B received one ml per kg of caudal dexmedetominine and 1µ/kg of clonidine analgic quality was assessed by FLACC score, it was 593 minutes in clonidine group compared to bupivacaine group alone.

Isik B et al.,[24]

They did a randomised, double blinded study on children undergoing MRI procedures by administration of intravenous dexmedetomine 1µ/kg reduces emergence agitation after sevoflurane anaesthesia. Anaesthesia was induced with sevoflurane 8% with O2:N2O 50:50% and maintained with sevoflurane 1.5%. One group received dexmedetomidine after induction of anaesthesia, other group does not receive any medication. SPO2, NIBP, HR was monitored every 5 minutes during procedures. Agitation score was assessed by 5 point scale. The agitation score of ≥4 for≥5 was considered delirium.mean agitation score in dexmedetomidine was significantly lower than placebo group.

Hansen TG et al.,[25]

They compared the effect of adding intravenous and caudal clonidine to caudal bupivacaine for post operative analgesia after hypospadiasis repair surgery. 46 children were randomly devided into two groups. One group received caudal clonidine 2µ/kg with 0.5ml of 0.25%bupivacaine. Other group received 2µ/kg clonidine intravenous injection with 0.5ml /kg of 0.25% bupivacaine group. Sedation score, motor block, require of rescue analgesia morphine was assessed. They

concluded that intravenous or caudal route has same duration of postoperative analgesia. It was statiscally not significant.

Ashraf Abdul Baki Abdul Baset .M.D et al,[26]

They **conducted** a study to evaluate the analgesic properties of dexmedetomidine alone or in combination with bupivacaine 0.125% when administered as an epidural infusion for the treatment of postoperative pain in patients undergoing extensive abdominal surgery. Ninety adult patients scheduled for abdominal surgery were studied. An epidural catheter was inserted in all patients at the T8-T9 vertebral interspace and a 15 ml of 0.5% bupivacaine injected epidurally. General anaesthesia was induced with propofol and atracurium and was maintained with a sevoflurane. VAS was used for assessment of postoperative pain and when it reaches 30, patients were then randomly divided into three groups to receive an epidural infusion at 10 mL/h of bupivacaine 0.125%, dexmedetomidine 0.5 µg/kg/hr in bupivacaine 0.125% and dexmedetomidine 0.5 µg/kg/hr diluted in 0.9% saline in Group B, Group DB, and Group D, respectively. VAS score, sedation score, sensory and motor blockade, MAP and HR were monitored and recorded. Rescue analgesia was given in the form of patient controlled analgesia and the total

morphine requirements were recorded together with the time to first analgesic requirement. The Group DB having the lowest morphine requirements (11.9 ± 15.6 mg) and the longest interval before analgesia was requested (12.0 ± 6.5 hr) while Group B, had the shortest period (4.0 ± 4.6) and the highest requirement (34.9 ± 20.7) *P* < 0.05. VAS were generally satisfactory for all groups, the mean score being below 30 mm. MAP and HR were similar in groups (D and DB), both were significantly lower than in Group B (P< 0.05), however such difference was not thought to be of clinical importance. The motor block was more significant in-group B and DB compared with group D in the PACU and up to 6 h post infusion (P <0.05 compared with dexmedetomidine group) While sensory blockade was more pronounced in the combination group. He concluded that patients undergoing abdominal surgery, the addition of the α_2-adrenergic agonist dexmedetomidine to epidural infusions of bupivacaine significantly improved postoperative analgesia without significant side effects.

Antonio Mauro Vieira et.al [27]

They conducted a study to evaluate the analgesia and sedation promoted by clonidine or dexmedetomidine associated to epidural ropivacaine in the postoperative period of subcostal cholecystectomy.

Clonidine and dexmedetomidine are α-2-adrenergic agonists with analgesic proprieties which potentiate local anaesthetic effects when epidurally administered. Forty patients of both gender were participated in this randomized double-blind study, aged 18 to 50 years, weighing 50 to 100 kg, physical status ASA I or II, submitted to subcostal cholecystectomy. The subjects were distributed in two groups: Clonidine (CG) received clonidine (1 mL = 150 μg) associated to 0.75% epidural ropivacaine (20 mL); Dexmedetomidine (DG) received dexmedetomidine (2 μg/kg) associated to 0.75% epidural ropivacaine (20 mL). Analgesia and sedation were evaluated 2, 6 and 24 hours after anesthetic recovery. Both groups presented some grade of sedation at 2 and 6 hours, with statistically significant difference between the two moments for the dexmedetomidine group. There has been analgesia in both groups, especially at 2 and 6hours. There has been statistically significant difference among periods of 2, 6 and 24 hours in the dexmedetomidine group; in the clonidine group, this statistically significant difference was observed between the periods of 2 and 6 hours and between 2 and 24 hours. To conclude that the association of clonidine or dexmedetomidine to 0.75% ropivacaine induces analgesia and sedation in 2 and 6 hours after anaesthetic recovery in patients submitted to subcostal cholecystectomy and that clonidine promotes more prolonged analgesia.

MATERIALS AND METHODS

This study was a randomised prospective single blinded study. This was conducted with approval of institutional ethical committee and written informed consent of parents or guardian. Patients who satisfied our inclusion criteria were divided into two groups - group B and Group BD.

INCLUSION CRITERIA:

- Age : 1year to 8 years
- ASA : 1 & 2,
- Surgery: Elective lower abdominal surgery
- Duration: Less than 120 minutes

EXCLUSION CRITERIA:

- Patients with suspected coagulopathy and History of liver disease
- Infection at the site of caudal block
- Uncontrolled systemic disorders
- H/O Developmental delay, Neurological disease
- Known allergy to study drugs
- Skeletal deformities

MATERIALS USED:

- Laryngoscopes of various sizes,
- Gum elastic bougie
- Guedel's oropharyngeal airway
- Drugs – propofol, sevoflurane, normal saline, inj atropine, succinylcholine ,inj ephedrine and other emergency drugs.
- Monitors – ECG , NIBP, SPO2, temperature monitoring.
- 2 cc,5 cc and 10 cc syringe
- 22G,24 G intravenous cannula.
- 23 G IM needle.
- Appropriate size endotracheal tubes/ Laryngeal Mask airway
- Dexmeditomidine 50 mic/ml 1ml ampoule
- bupivacaine 20ml vial 0.5%

PRIMARY PARAMETERS Noted were

- Ramsay sedation scale
- FLACC Pain Score and
- Duration of Analgesia

SECONDARY OUTCOME MEASURES:

- Heart rate,
- Systolic, Diastolic, and Mean Blood Pressure ,
- SpO_2
- Any adverse effects

CONDUCTION OF THE STUDY

A prospective randomized control study was done to compare the effect of adding dexmedetomidine to caudal bupivacaine and caudal bupivacaine alone for providing postoperative analgesia in children undergoing lower abdominal surgeries.

The clinical study was conducted at our hospital in anaesthesiology department. Sixty children between the age group 1 to 8 years scheduled for elective lower abdominal surgeries were randomly divided into two groups for study. The age and weight of child was recorded. All children had their last feed at about 4.00am on the day of surgery.

Group B-received caudal epidural block with 1ml/kg of 0.25% bupivacaine

Group BD-received caudal epidural block with 1ml/kg of 0.25% Bupivacaine and 1microgram /kg of dexmedetomidine

All the operations were carried out under general anaesthesia. precordial stethoscope, pulse oxymeter. NIBP,ECG,SPO2 monitors were attached. basal parameters were noted. Intravenous line was secured with 22 G IV cannula onto a vein on the dorsum of hand.

Anaesthesia was induced in the theatre with propofol at a dose of 2 mg/kg along with O2 100% with fresh gas flow of 6 L/minute with sevoflurane 2 to 3 %. an appropriate sized LMA was positioned in situ, bilateral air entry was checked and LMA was fixed. anaesthesia was maintained with 67% N20 &33% O2 and sevoflurane 1to 2% using Jackson Rees modifications of ayre's 'T' piece with the patient in spontaneous respiration.

After induction of general anaesthesia, GROUP B received caudal epidural block with 1ml/kg of 0.25% bupivacaine, Group BD-received caudal epidural block with 1ml/kg of 0.25% Bupivacaine and 1microgram /kg of dexmedetomidine

Using 23G needle. Intraoperatively balanced salt solution 20ml/kg/hour was infused. Heart rate,respiratory rate ,blood pressure were recorded at an interval 5 minutes. Block failure was considered if rise in heart rate or MAP more than 20% of pre incision values. Inj fentanyl 1 mcg/kg iv was given in these patients were pain relief.

Children were extubated in deep plane of anaesthesia. Children shifted to PACU haemodynamics were continuously were monitored for 24 hours.

Post-op Sedation was assessed using ***ramsay sedation score*** as follows:

I. Anxious, agitated or both
II. Co-operative oriented, tranquil
III. Response to commands only
IV. Brisk response to loud auditory stimulus
V. Sluggish response to loud auditory stimulus
VI. No response to loud auditory stimulus

Pain was assessed by using FLACC pain scale, rescue analgesia of Syp. Paracetamol 15mg/kg given at pain score 4 or above.

Pulse rate, NIBP, and complications like nausea and vomiting, urinary retention, and respiratory depression etc. Bradycardia was considered if heart rate less than 60/min and treated with injection atropine , hypotension was considered when systolic blood pressure was below 70 plus twice age in years with altered tissue perfusion. Number of patients requiring fluid bolus to treat hypotension noted. Respiratory depression was considered if SpO_2 fell below 95%.

Oral feeds were allowed after 6 hours. All the children were examined prior to discharge for clinical evaluation of neurological system

OBSERVATION AND RESULTS

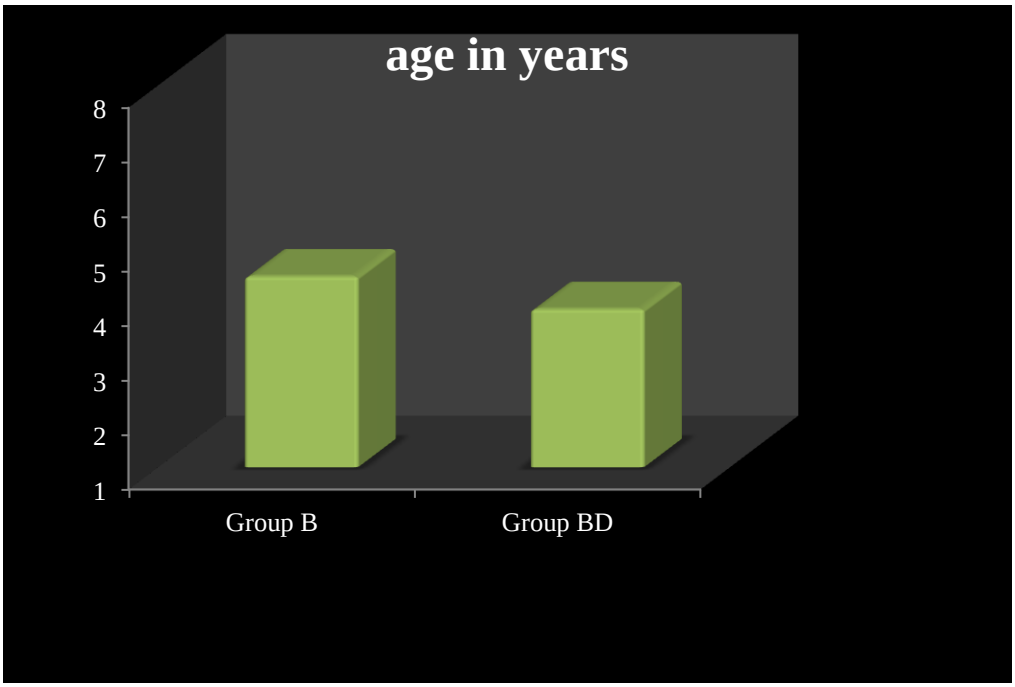
STATISTICAL ANALYSIS

Results are expressed as mean and standard deviation. All statistical analyses were carried out using SPSS for Windows version 15.0. Statistical analysis was carried out by student's t-test for parametric data and chi square test, fischer's exact test for non parametric data. Heart rate, systolic, diastolic and mean arterial pressure were compared using student's t-test. A p value < 0.05 was considered as statistically significant.

Both the groups were comparable in terms of age, sex, weight and duration of surgery.

Table 1: Demographic Profile: Age

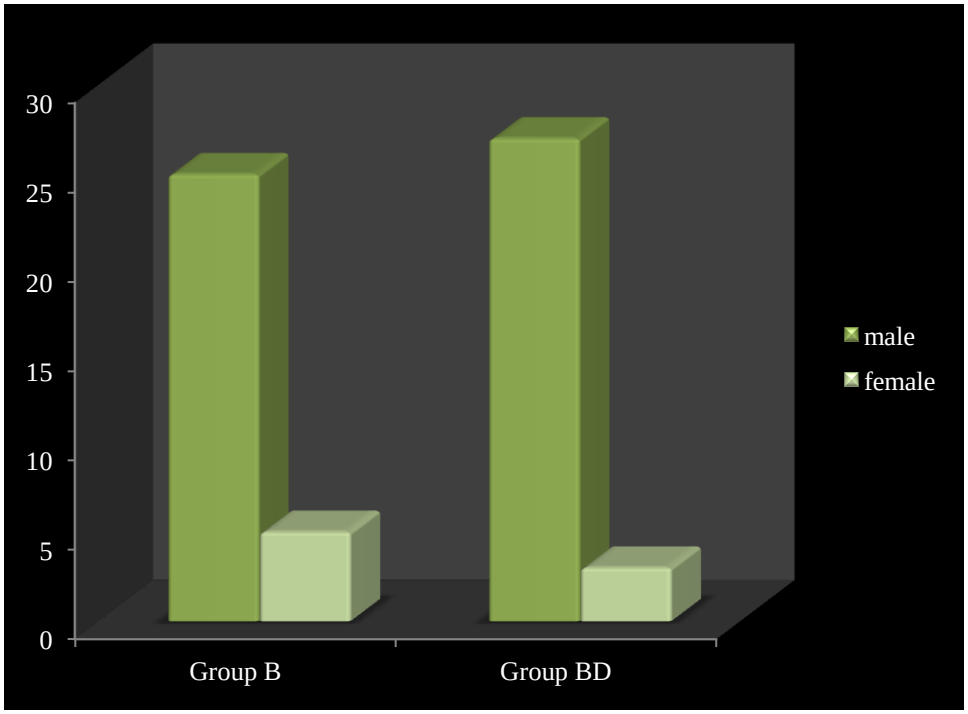
group	N	Mean ±standard deviation	P value
Group B	30	4.5±1.96	0.267
Group BD	30	3.9±1.83	



There was no statistically significant difference in between the two groups in terms of age.

Table 2: Demographic Profile : Sex

sex	Group B		Group BD		P value
	No	%	no	%	
male	25	83.3	27	90	0.448
female	5	16.7	3	10	



There was no statistically significant difference in between the two groups in terms of sex ratio.

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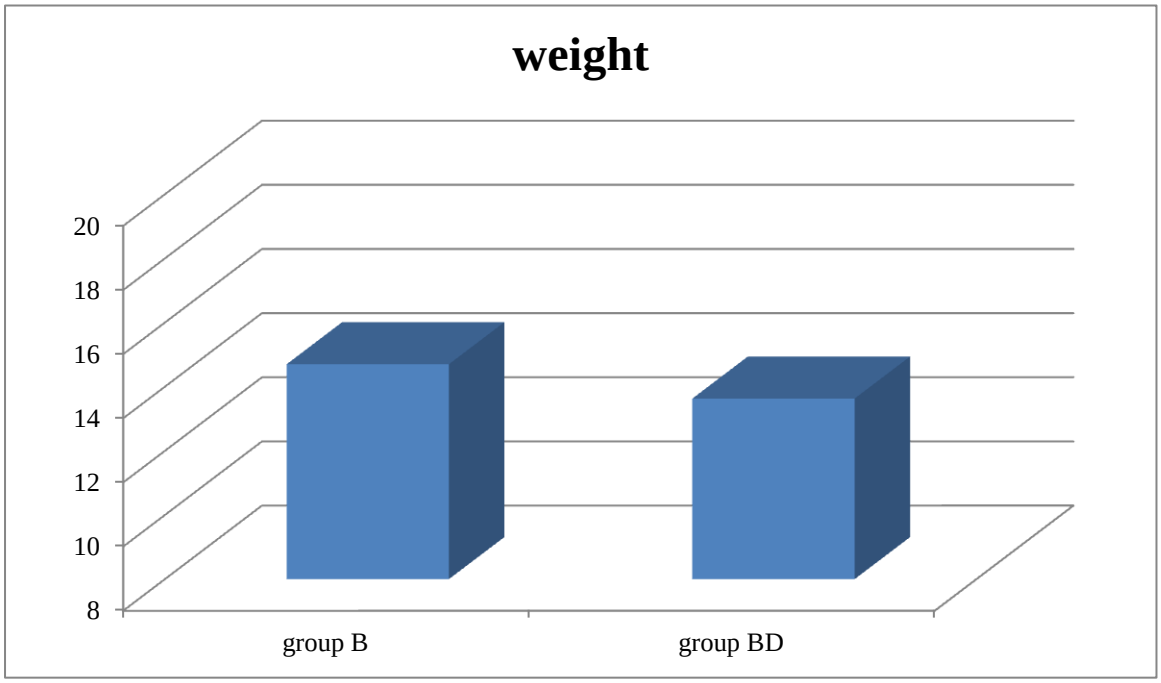
Table no 3: Demographic Profile Weight

Group	N	mean± standard deviation	P value
Group B	30	14.7±3.38	0.226
Group BD	30	13.63±3.48	



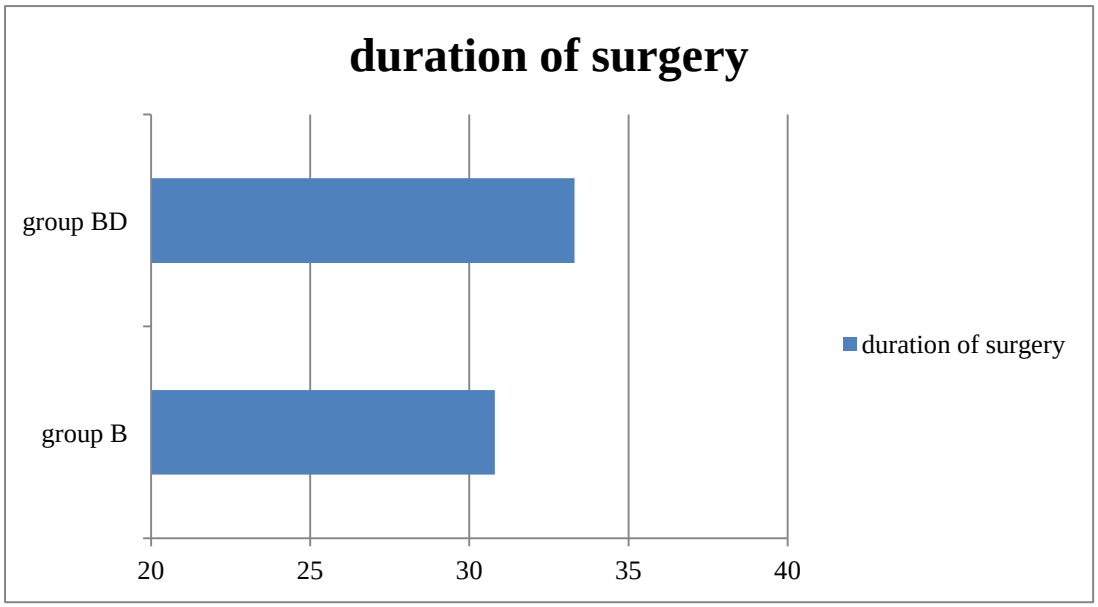
There was no statistically significant difference in between the two groups in terms of distribution of weight.

Table 4: Comparison of Type of Surgery

Surgery	Group B		Group BD		P value
	no	Percentage	No	Percentage	0.934
circumcision	11	36.7%	10	47.6%	
herniotomy	11	36.7%	10	47.6%	
Hydrocele	5	16.7%	7	23.3%	
Orchidopexy	8	10%	3	10%	

.Duration of surgery

	group	N	mean±standard deviation	P value
weight	Group B	30	30.8±6.8	0.127
	Group BD	30	33.3±5.6	



There was no statistically significant difference in between the two groups in terms of type of surgery or the duration of surgery

Table 6: Duration of Analgesia

Group	Mean± Std. Deviation	p value
Group B	307.33± 31.588	0.000
Group BD	682.33± 74.310	

Mean duration of analgesia in group B was 307.33± 31.588 minutes and in group BD was 682.33± 74.310 minutes .We found that the duration of analgesia was significant better with a p value of 0.000.

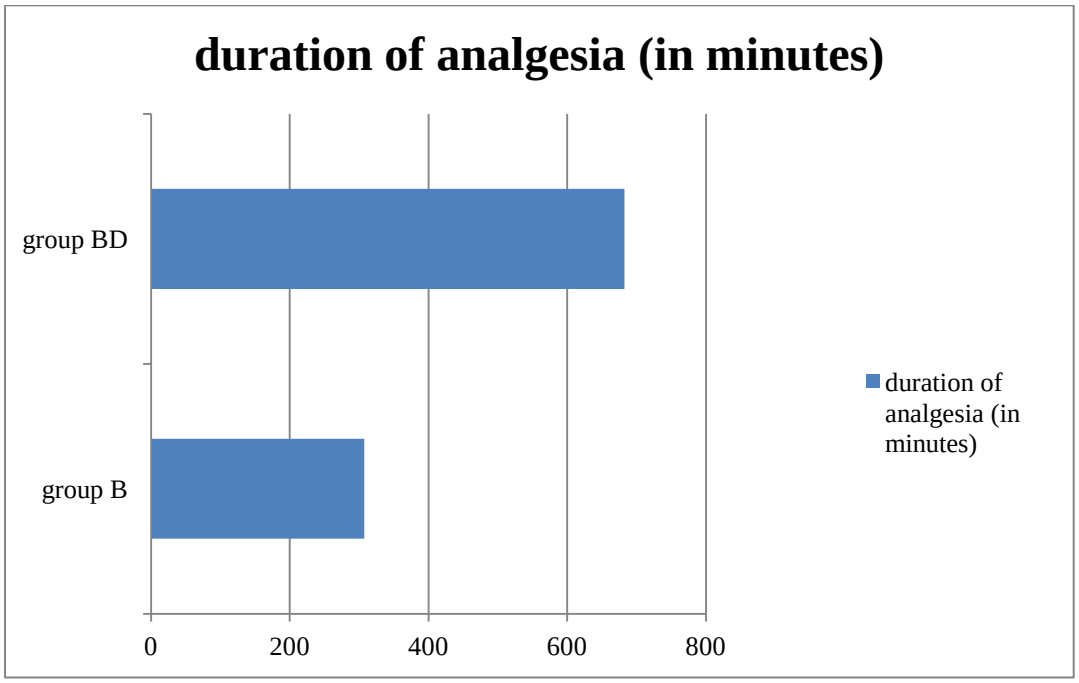


Table 7: FLACC Score of the Two Groups

Time	N		Group B	Group BD	p value
0 hour	30	30	0.00±.000(a)	0.00±0.000(a)	0.326
2nd hour	30	30	.07±.365	0.00±.000	0.000
4th hour	30	30	2.63±.964	.03±.183	0.000
6th hour	30	30	3.96±.204	.40±.724	0.000
8th hour	1	30	4.00	1.83±.913	0.027
12th hour	0	16	-	3.88±.342	-
16th hour	0	2	-	4.00±0.000	-

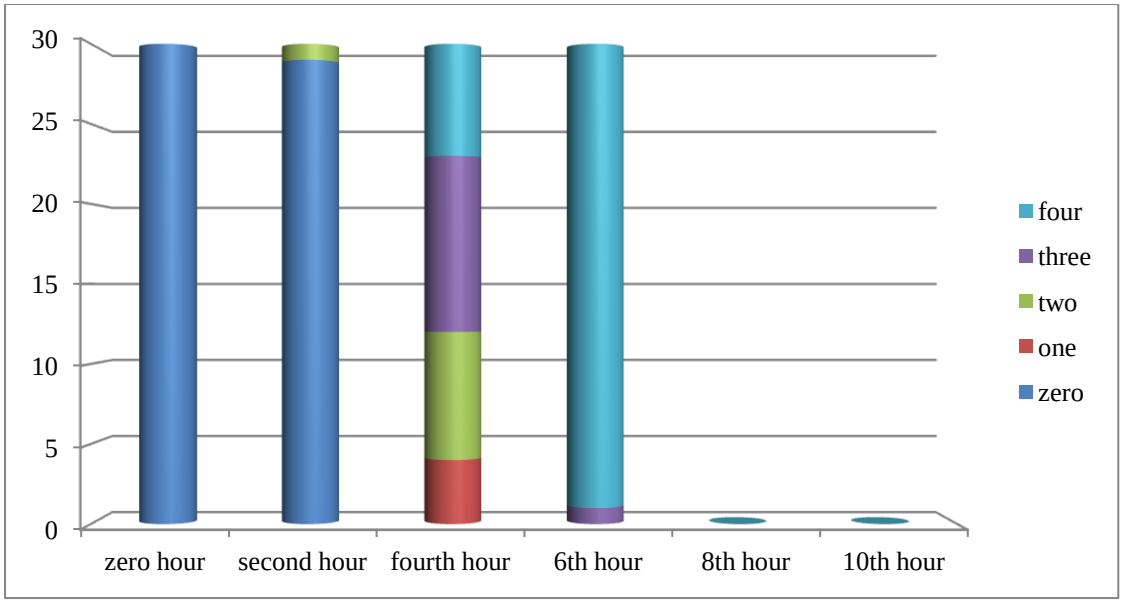
Effective analgesia as indicated by the FLACC score of less than 4 was observed for upto 8 hours in the bupivacaine with dexmedetomidine group and upto 4 hours in bupivacaine with saline group postoperatively.

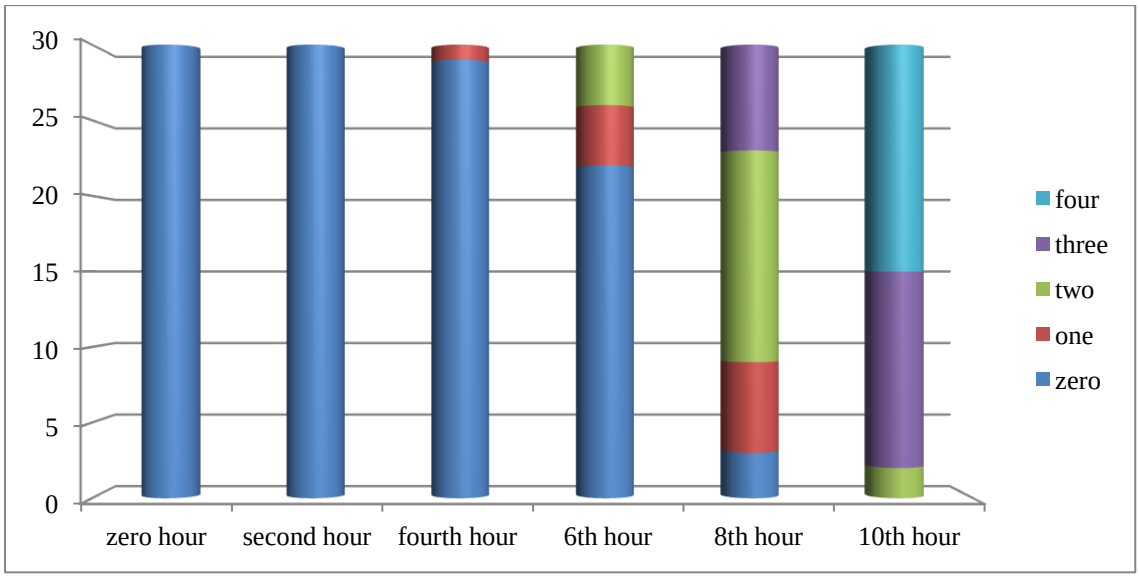
The difference in FLACC score between the two groups was highly significant.

Table 8: FLACC Score Frequency Distribution

FLACC score ➡ hours ⬇	zero		one		two		three		Four		total	
	B	BD	B	BD	B	BD	B	BD	B	BD	B	BD
0 hour	30	30	-	-	-	-	-	-	-	-	30	30
2nd hour	29	30	-	-	1	-	-	-	-	-	30	30
4th hour	-	29	4	1	8	-	11	-	7	-	30	30
6th hour	-	22	-	4	-	4	1	-	29	-	30	30
8th hour	-	3	-	6	-	14	-	7	-	-	-	30
10th hour	-	-	-	-	-	2	-	13	-	15	-	30

This table shows the frequency distribution of FLACC score among the two groups over the period of 10 hours. The FLACC Score was better with group BD over the entire period.

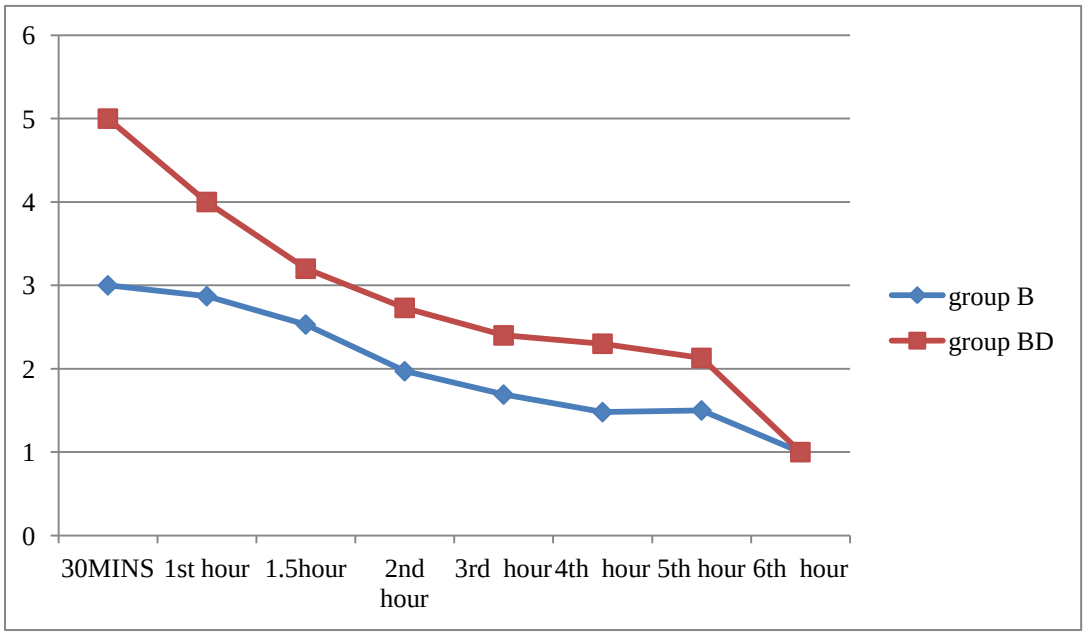




FLACC score measured every 4th hour showed that the score was significantly better in group BD. 7 and 29 patients had score of 4 in group B compared to zero patients in group BD. Score of 4 was attained only at the 10th hour in group BD in 15 patients

Table 9: The Ramsay Sedation Score of the Two Groups

	N		Group B	Group BD	P value
30MINS	30	30	3.00±0.000(a)	5.00±0.000	0.000
1st hour	30	30	2.87±0.346	4.00±0.000	0.000
1.5hour	30	30	2.53±0.507	3.20±0.407	0.000
2nd hour	30	30	1.97±0.183	2.73±0.521	0.000
3rd hour	30	30	1.69±0.471	2.40±0.498	0.000
4th hour	21	30	1.48±0.512	2.30±0.466	0.000
5th hour	10	30	1.50±0.527	2.13±0.434	0.000
6th hour	3	30	1.00±.000(a)	1.00±1.00	0.001



Adequate sedation as indicated by Ramsay's sedation score of 2 was observed upto 1and half hours in bupivacaine with saline group and upto 4 hours in the bupivacaine with dexmedetomidine group.

This showed that the sedation was better with dexmedetomidine group when compared to the saline group. It was statistically significant p value less than 0.001

Table 10: Intra Operative Systolic Blood Pressure of The Two Groups

	Group B	Group BD	p value
Baseline	104.63±17.06	102.97±16.73	0.704
After induction	96.3±11.32	94.4±12.92	0.547
5 minutes	96.97±11.63	94.17±9.62	0.314
10 minutes	97.27±8.85	93.67±10.01	0.146
15minutes	95.60±10.92	93.73±9.94	0.492
20minutes	95.69±9.29	92.70±9.28	0.221
25minutes	95.52±7.81	93.53±8.59	0.367
30 minutes	96.26±6.52	94.50±8.75	0.463

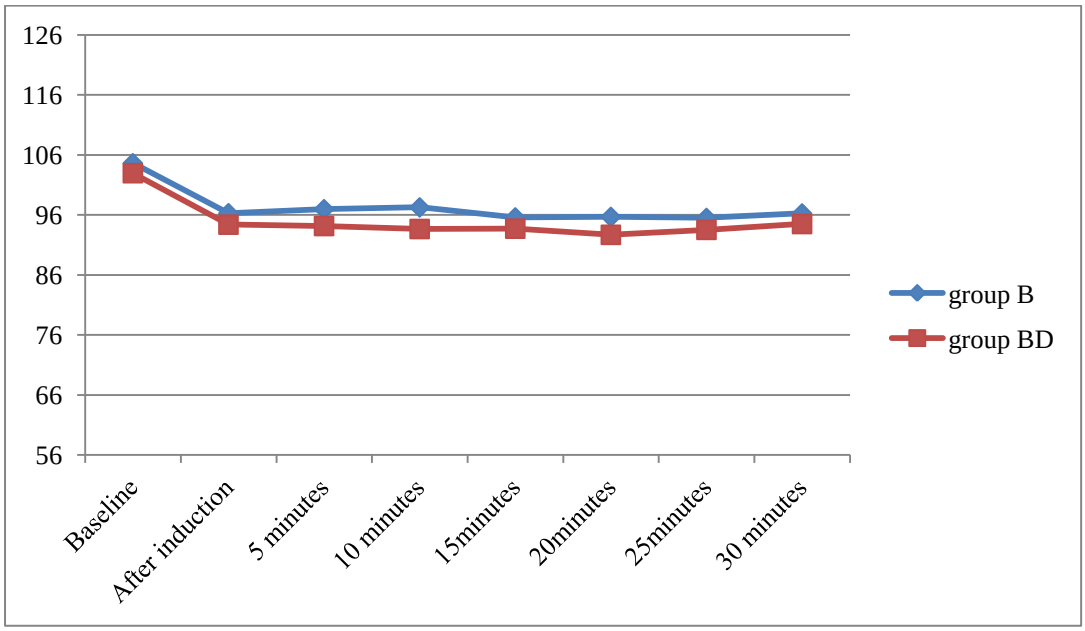
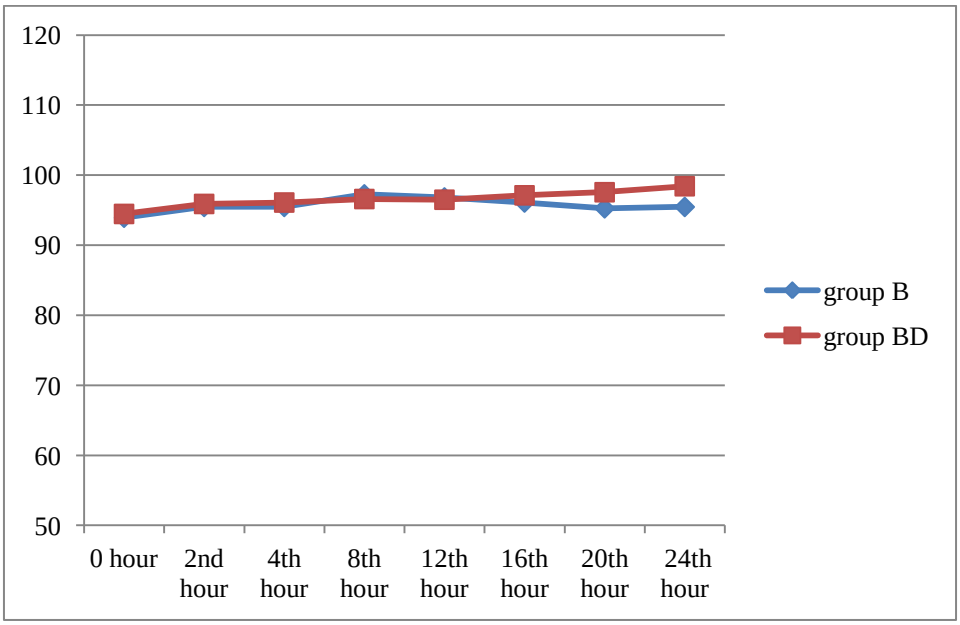


Table 11: Post-Operative Systolic Blood Pressure

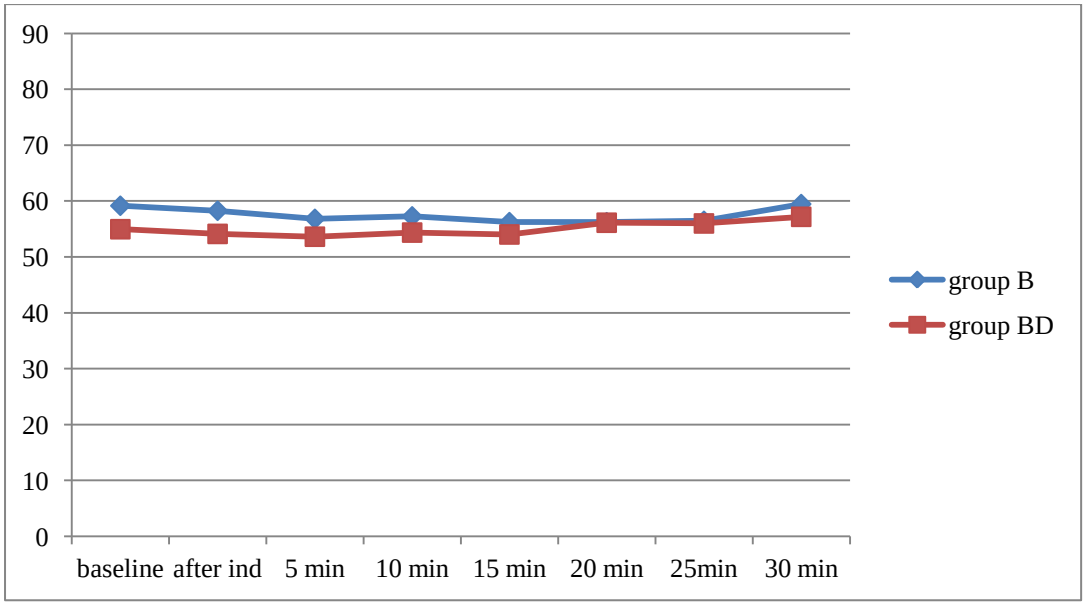
	Group B	Group BD	p value
0 hour	93.93±6.602	94.47±8.65	0.789
2nd hour	95.47±7.89	95.90±.628	0.840
4th hour	95.47±5.47	96.10±8.462	0.755
8th hour	97.27±9.868	96.60±9.561	0.791
12th hour	96.83±8.158	96.50±9.35	0.884
16th hour	96.10±7.275	97.13±9.18	0.631
20th hour	95.27±6.66	97.57±10.21	0.307
24th hour	95.47±7.749	98.43±98.43	0.199



The systolic blood pressure was comparable between the groups both in the intra-operative and post-operative period.

Table 12: Comparison of Mean of Diastolic Blood Pressure Between The Two Groups- Intra-Operative Period

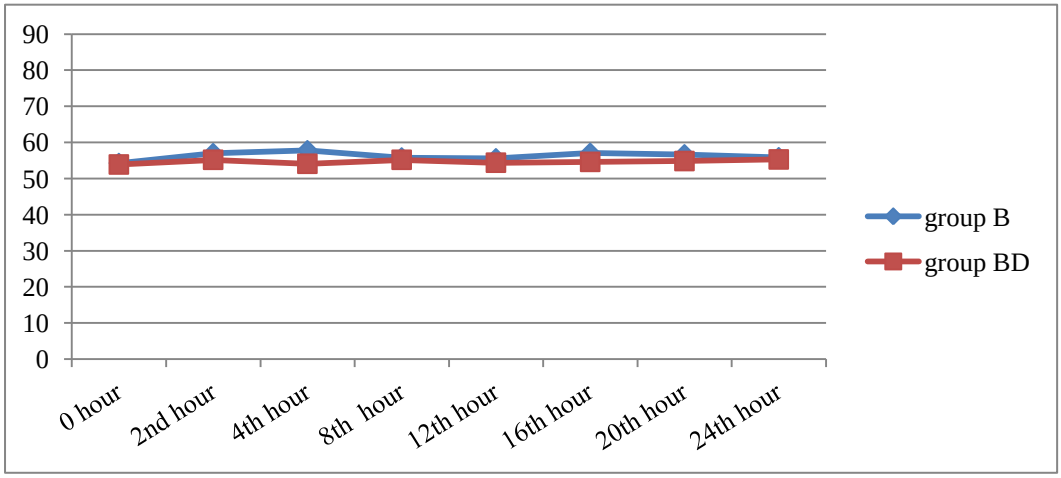
	N	Group B	Group BD	p value
Baseline	30	56.17±7.12	54.97±6.89	0.051
After induction	30	56.27±6.72	54.13±2.99	0.195
5 minutes	30	56.83±6.39	53.63±5.81	0.047
10 minutes	30	56.83±7.33	54.37±5.38	0.159
15 minutes	30	57.27±7.38	54.03±11.0	0.199
20 minutes	30	56.24±7.00	56.13±6.03	0.950
25minutes	30	56.22±6.76	56.00±6.06	0.897
30 minutes	30	59.47±6.41	57.19±6.77	0.255



The mean diastolic blood pressure was comparable between the groups in the intra-operative period.

Table No 13: Comparison of Mean of Diastolic Blood Pressure Between The Two Groups- Post-Operative Period

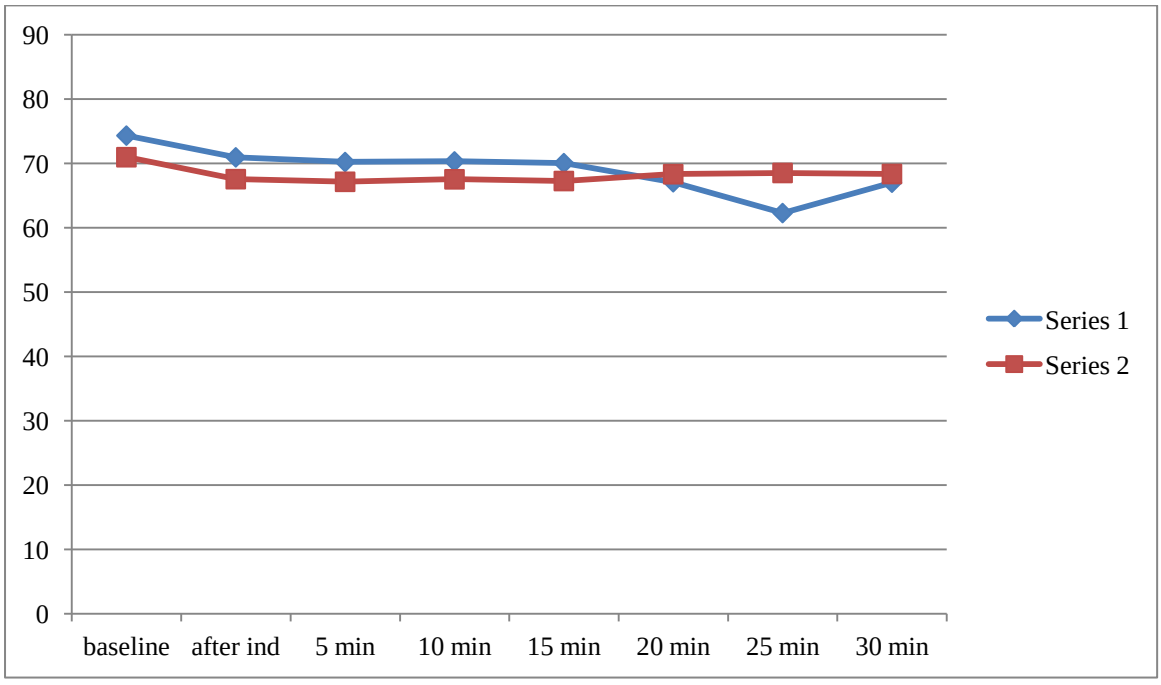
Time	N	Group B	Group BD	p value
0 hour	30	54.27±6.55	53.87±5.34	0.652
2nd hour	30	57.00±6.98	55.17±5.65	0.268
4th hour	30	57.80±8.63	54.07±6.38	0.62
8th hour	30	55.80±6.65	55.17±7.24	0.726
12th hour	30	55.57±6.74	54.37±6.72	0.493
16th hour	30	57.07±7.34	54.60±7.00	0.194
20th hour	30	56.67±9.94	54.83±6.08	0.393
24th hour	30	55.87±6.37	55.27±5.343	0.721



The mean diastolic blood pressure was comparable between the groups in the post-operative period.

Table 14: Mean Arterial Pressure Intra operative Period In Both The Groups

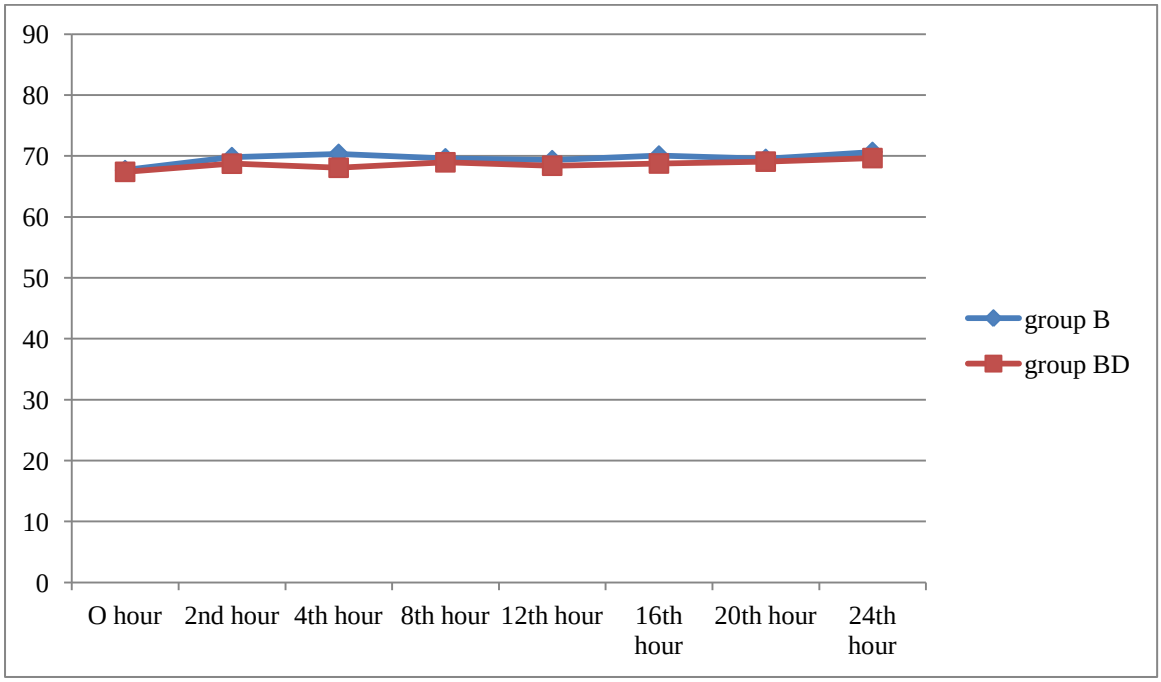
	N	Group B	Group BD	p value
Baseline	30	74.32±9.28	70.96±9.10	0.163
After induction	30	70.94±6.67	67.55±7.32	0.060
5 minutes	30	70.21±6.93	67.14±6.46	0.082
10 minutes	30	70.31±7.04	67.53±5.91	0.103
15 minutes	30	70.04±7.51	67.26±8.34	0.181
20 minutes	30	67.07±14.31	68.32±6.00	0.663
25 minutes	30	62.38±21.93	68.51±6.00	0.146
30 minutes	30	67.00±7.24	68.35±5.09	0.661



The mean arterial blood pressure was comparable between the groups both intra-operative period.

Table 15: Mean arterial pressure post-operative period in both the groups

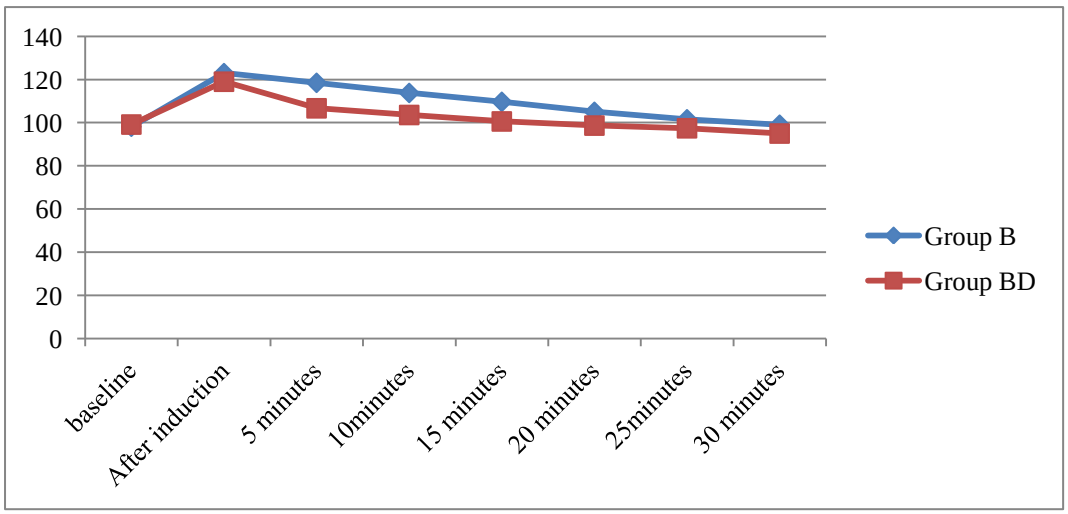
time	N	Group B	Group BD	p value
O hour	30	67.68±6.05	67.40±5.80	0.851
2nd hour	30	69.82±6.44	68.74±5.63	0.632
4th hour	30	70.35±7.27	68.07±6.27	o.381
8th hour	30	69.62±6.91	68.97±7.37	0.836
12th hour	30	69.32±6.60	68.41±6.79	0.560
16th hour	30	70.07±6.70	68.77±6.39	0.493
20th hour	30	69.53±7.63	69.08±6.19	0.199
24th hour	30	70.67±6.17	69.66±5.71	0.728



The mean blood pressure was comparable between the groups in the post-operative period.

Table 16: Comparison of Intra-operative heart rate between the two groups.

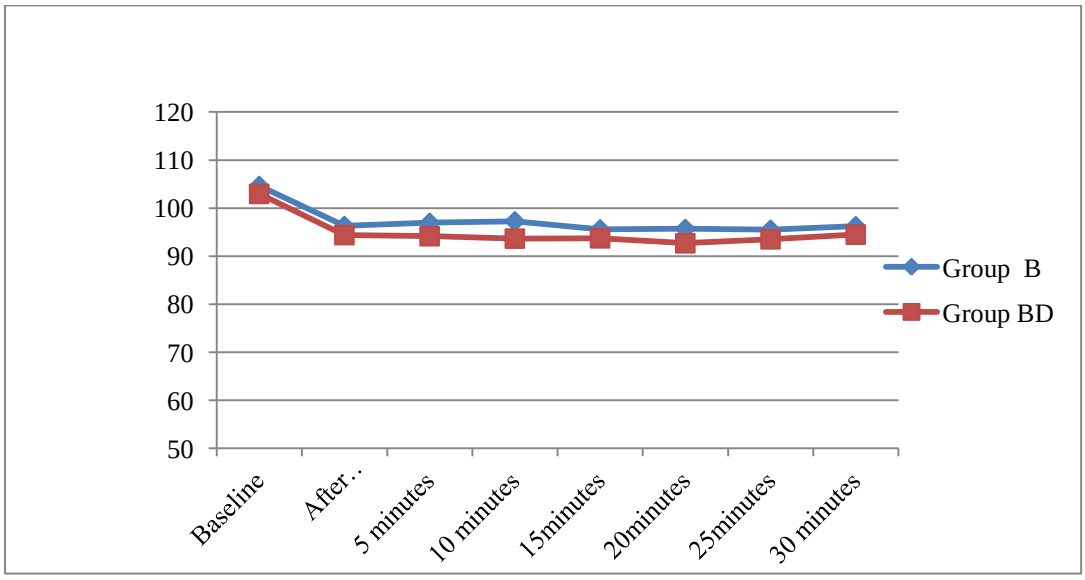
Minutes	number	Group BD	Group B	p value
Baseline	30	99.17±7.85	98.17±7.13	0.608
After induction	30	119±9.49	123±8.50	0.188
5 minutes	30	106.7±8.50	118.5±9.61	0.000
10minutes	30	103.6±7.66	113.8±8.84	0.000
15 minutes	30	100.6±6.6	109.7±8.2	0.000
20 minutes	30	98.69±6.53	105.07±6.78	0.001
25minutes	30	97.44±6.75	101.6±8.1	0.016
30 minutes	30	95.0±8.1	99.08±5.080	0.029



There was statistically significant difference noted between the two groups in intraop heart rate with p value of less then 0.05

Table 14: Comparison of post -operative heart rate between the two groups.

	number	Group B	Group BD	p value
0 hour	30	95.9±4.84	93.7±6.60	0.159
2nd hour	30	89.3±6.85	90.5±9.03	0.543
4th hour	30	91.03±6.18	90.63±7.41	0.821
8th hour	30	91.87±6.37	88.6±5.34	0.246
12th hour	30	91.13±6.34	89.6±5.34	0.311
16th hour	30	91.47±6.08	89.6±6.18	0.156
20th hour	30	90.97±5.85	90.7±5.48	0.856
24th hour	30	91.93±5.75	91.93±5.76	0.888



There was no significant difference in the mean heart rate between the two groups in post-operative period

DISCUSSION

Caudal analgesia is one of the easiest and safest technique for providing pain relief, both in children and adults, with a very high success rate. Apart from providing adequate intra-operative and post-operative analgesia, it is beneficial in various ways. It reduces the stress hormone levels produced during anaesthesia. It reduces the intraop and postop analgesic requirements in the form of narcotics and NSAIDs. It also helps in early ambulation and less hospital stay, thereby alleviating most of the anxiety and burden of the child's parents.

Local anaesthetics alone, especially Bupivacaine, were commonly used in the past in caudal technique for providing pain relief. Though it has produced excellent analgesia, the analgesia was found to be short lived and required additional analgesic requirements in the postoperative period. This resulted in excessive use of opioids like morphine postoperatively, which resulted in significant respiratory depression and PONV(Post Operative Nausea and Vomiting). Though caudal continuous catheter technique was found as an alternative to provide analgesia throughout the postoperative period, it had its own disadvantage of producing severe catheter related infections.

This resulted in the usage of various adjuvants to the local anaesthetics to prolong their analgesic effect postoperatively, like morphine, adrenaline, ketamine, neostigmine, clonidine etc..

One such adjuvant used was dexmedetomidine, a newer alpha-2 agonist. This drug had various advantages when compared other adjuvants which were used in the past, in providing extended duration of analgesia with good sedation(arousable sleep) without producing respiratory depression, which gained its popularity in the recent time.

Our study was done to evaluate the analgesic efficacy of dexmedetomidine with bupivacaine in caudal analgesia.

FLACC SCORE:

The bupivacaine with saline group(group B) and the bupivacaine with dexmedetomidine group(group BD) were compared with respect to the FLACC scores achieved at various interval of time (0 hr, 2^{nd} hr, 4^{th} hr and every 4 hours thereafter). The FLACC score of less than 4 was assumed as effective analgesia.

The FLACC score was comparable between the groups in the 2^{nd} hour postoperatively. After the second hour, the FLACC scores differed significantly between the groups($p<0.05$). At the 4^{th} hour postoperatively, the FLACC score in bupivacaine group was 2.6±0.9

and in bupivacaine with dexmedetomidine group was 0.03±0.18, which was statistically significant(p=0.000).

At the 6th hour postoperatively, the FLACC score in bupivacaine group was 3.9±0.2 and in bupivacaine with dexmedetomidine group was 0.4±0.72, which was statistically significant(p=0.000). At the 8th hour postoperatively, the FLACC score in bupivacaine group was 4 and in bupivacaine with dexmedetomidine group was 1.8±0.91, which was statistically significant(p=0.027).

Effective analgesia as indicated by the FLACC score of less than 4 was observed for upto 8 hours in the bupivacaine with dexmedetomidine group and upto 4 hours in bupivacaine with saline group postoperatively.

This shows that the effective analgesia lasted longer in bupivacaine with dexmedetomidine when compared to bupivacaine group.

This finding closely correlates with the results of the study done by **Vijay G anand et** al where ropivacaine with dexmedetomidine attained FLACC score of 4 at 16th hour and ropivacaine alone group attained it at 6th hour postoperatively($p<0.001$).

This is also supported by the study done by **Hannawy et al** where FLACC score of 4 was attained at 16^{th} hour in the bupivacaine with dexmedetomidine (2 mcg/kg) group($p<0.001$).

This is also supported by **Sadawy et al FLACC** score of 4 was attained at 18.2 hour in bupivacaine with dexmedetomidine group compared with 2.8 hours in bupivacaine group.

SEDATION SCORE:

Sedation score was analysed between the two groups at various interval of time(30^{th} min, 1^{st} hr, 1.5^{th} hr, 2^{nd} hr, 3^{rd} hr, 4^{th} hr, 5^{th} hr and 6^{th} hr postoperatively). Ramsay's sedation score of atleast 2(co-operative, oriented, tranquil) was assumed as adequate sedation.

- No patient had sedation score of 6(unresponsive patient).
- At 30^{th} minute, the sedation score observed was 3 in the bupivacaine group and 5 in the bupivacaine with dexmedetomidine group.
- At 1^{st} hour postoperative period, the sedation score observed was 2.87±0.34 in the bupivacaine group and 4 in the bupivacaine with dexmedetomidine group, which was statistically significant($p=0.000$)

- At 1.5th hour postoperative period, the sedation score observed was 2.03±0.50 in the bupivacaine group and 3.20±0.4 in the bupivacaine with dexmedetomidine group, which was statistically significant(p=0.000)
- At 2nd hour postoperative period, the sedation score observed was 1.97±0.18 in the bupivacaine group and 2.73±0.52 in the bupivacaine with dexmedetomidine group, which was statistically significant(p=0.000)
- At 3rd hour postoperative period, the sedation score observed was 1.69±0.47 in the bupivacaine group and 2.47±0.49 in the bupivacaine with dexmedetomidine group, which was statistically significant(p=0.000)
- At 4th hour postoperative period, the sedation score observed was 1.48±0.51 in the bupivacaine group and 2.30±0.46 in the bupivacaine with dexmedetomidine group, which was found to be statistically significant(p=0.000)
- At 5th hour postoperative period, the sedation score observed was 1.5±0.52 in the bupivacaine group and 2.13±0.43 in the bupivacaine with dexmedetomidine group, which was found to be statistically significant(p=0.001)

Adequate sedation as indicated by Ramsay's sedation score of 2 was observed upto 1and half hours in bupivacaine with saline group and upto 4 hours in the bupivacaine with dexmedetomidine group.

This showed that the sedation was better with dexmedtomidine group when compared to the saline group.

The results were similar to the study conducted by **Vijay G Anand et al**, where they have found that the sedation score was better with the ropivacaine-dexmedetomidine group when compared to ropivacaine alone.

This results were similar to the study conducted by **Sadawy et al., Hennawy et al** dexmedetomidine group have better sedation score compared to bupivacaine group.

DURATION OF ANALGESIA:

The duration of analgesia was compared between the groups. For bupivacaine with saline group, the mean duration of analgesia was about 307±31 mins and for the bupivacaine with dexmedetomidine group, it was about 682±74 mins. This difference was statistically significant with a p value of about 0.000.

This closely correlates with the **Vijay G Anand et al** study, where the duration of analgesia was higher in the ropivacaine with dexmedetomidine group(14.5hrs) when compared to the ropivacaine alone group(5.5hrs), which was statistically significant($p<0.001$). The longer duration of analgesia in dexmedetomidine group in this study when compared to our study, might probably be due to the varying amount of dexedetomidine administered (2 mcg/kg in this study and 1mcg/kg in our study).

HEMODYNAMIC CHANGES:

The heart rate changes were compared at various interval of time both intra operatively and postoperatively. The changes were statistically significant($p<0.05$) between the groups in the first half an hour of the surgery, where the heart rate was less in bupivacaine with dexmedetomidine group when compared to bupivacaine group. But these heart rate changes were manageable intraoperatively, without the need for inj. Atropine or any inotropic support.

Observation made in our study also concurs with **Hennawy et al** study regarding intra op significant decrease in heart rate. But the heart rate reduction in our study did not warrant the use of Inj Atropine like theirs.

There were no significant difference between the groups in terms of systolic blood pressure, diastolic blood pressure, mean arterial pressure and oxygen saturation.

These results were similar with **Hennawy et al., Vijay anand et al.,** regarding of systolic blood pressure, diastolic blood pressure, mean arterial pressure and oxygen saturation.

COMPLICATIONS:

No clinically significant complications noted in both the groups.

SUMMARY

This study was conducted to evaluate the efficacy of dexmedetomidine as an adjuvant to Bupivacaine in caudal analgesia for paediatric patients undergoing lower abdominal surgeries.

The following observations were made

- Duration of analgesia was higher in bupivacaine with dexmedetomidine (307 minutes)group when compared to the bupivacaine group(682 mins), which was statistically significant.
- FLACC scores for analgesic assessment was better in the bupivacaine with dexmedetomidine group when compared to bupivacaine group which was statistically significant. FLACC score less than 4 was seen for upto 8 hours in the group BD than group B which was upto 4 hours.
- Sedation score as assessed by Ramsay's sedation score was better with the bupivacaine with dexmedetomidine group when compared to the bupivacaine group which was statistically significant.
- Hemodynamic changes were minimal and manageable in both the groups.

CONCLUSION

We conclude that addition of Dexmedetomidine as an adjuvant to Bupivacaine provides prolonged analgesia and better quality of sedation with minimal hemodynamic changes when compared to Bupivacaine in caudal block for paediatric patients undergoing lower abdominal surgeries.

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GROUP-B					Control		MASTER CHART																																	
SL NO	NAME	AGE	SEX	WT	IP NO	SURGERY	DOS	HEART RATE																				SYSTOLIC BP														
								PERIOP								POSTOP									PERIOP								POSTOP									
								BI	AI	5'	10'	15'	20'	25'	30'	35'	40'	0'	2h	4h	8h	12h	16h	20h	24h	BI	AI	5'	10'	15'	20'	25'	30'	35'	40'	0'	2h	4h	8h	12h	16h	20h	24h
1	rajesh	4	m	15	2093/12	circumcision	25	94	122	118	108	99	93	88				90	76	94	96	92	100	90	102	84	93	88	86	90	85	88				88	85	86	87	86	90	92	90
2	regan	4.5	m	13	2066/12	herniotomy	35	102	128	122	118	108	104	102	98	94		97	91	98	100	101	96	90	93	100	108	94	98	101	98	94	96	97		97	92	100	104	104	108	101	102
3	abdul	5	m	20	2022/12	circumcision	20	96	113	106	102	96	94					94	94	97	100	92	95	91	93	107	100	90	94	96	97					98	97	91	98	100	102	100	104
4	vignesh	8	m	20	2088/12	herniotomy	40	88	132	114	103	102	108	102	99	94	95	99	92	98	103	93	88	90	93	122	106	102	97	94	95	97	99	100	100	104	94	91	97	100	92	94	110
5	dhinesh	1	m	8	2086/12	hydrocele	25	114	122	108	108	109	106	107				109	103	104	107	106	105	103	100	80	76	78	87	84	80	81				79	81	84	83	81	88	86	83
6	hari	2	m	10	2078/12	herniotomy	30	102	130	120	118	108	104	106	101			98	103	96	94	99	95	97	99	82	84	82	88	89	86	82	85			80	79	78	76	81	83	80	81
7	vasu	3	m	14	2067/12	circumcision	20	102	110	102	98	96	96					95	90	89	91	92	94	98	96	87	83	88	90	91	82					88	83	83	85	79	80	81	78
8	rahul	3	m	13	2015/12	orchidopexy	40	90	108	104	101	94	91	88	84	83	82	80	82	85	83	82	83	82	90	96	80	78	86	82	80	83	80	87	88	82	92	93	100	95	95	88	87
9	arun	7	m	18	2111/12	hydrocele	30	88	100	96	95	97	93	95	88			80	76	80	85	86	89	91	94	114	112	116	110	113	109	104	100			99	103	106	109	114	108	105	106
10	nithyasree	3	f	12	2114/12	herniotomy	35	95	98	96	95	94	95	96				90	89	95	96	97	98	100	96	90	95	92	88	89	85	89				86	91	96	100	94	93	91	96
11	mohan	3	m	12	2116/12	circumcision	15	95	110	106	101	98						98	89	81	91	98	92	97	93	94	90	89	91	96						92	94	97	100	93	95	94	89
12	samson	2	m	10	2130/12	hydrocele	30	95	114	112	108	106	104	98	94			94	86	88	92	95	87	87	90	90	80	94	92	83	86	91	97			91	91	94	96	94	92	88	99
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17	pradeep	3	m	12	2340/12	circumcision	35	100	120	114	116	108	105	104	102	100		96	96	95	96	99	96	89	88	95	96	90	88	86	87	89	85	86		90	92	93	95	92	91	92	88
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19	hemakumar	4	m	14	2355/12	circumcision	25	90	96	94	97	96	92	90				88	85	94	90	82	98	94	97	90	85	88	91	94	96	97				98	97	95	102	100	98	97	95
20	jeeva	4	m	13	2333/12	hydrocele	25	90	105	108	102	101	99	98				95	95	99	92	94	94	92	93	98	100	96	95	98	94	96				100	107	106	102	99	97	95	97
21	guru	4	m	15	2341/12	herniotomy	30	88	106	108	106	102	100	99	96			96	93	92	98	92	94	96	98	110	96	98	100	62	95	97	98			95	98	99	104	95	96	97	93
22	jothi	5	f	18	2347/12	herniotomy	35	86	99	93	96	97	95	94	92	93		93	89	88	82	84	83	82	81	114	96	100	102	98	99	101	98	98		98	98	95	104	99	94	97	96
23	seenu	5	m	17	2317/12	circumcision	35	86	99	96	97	94	95	97	96	95		90	82	81	80	86	90	82	84	116	100	96	98	101	108	106	102	103		96	100	102	110	103	96	98	97
24	karthiga	5	f	17	2318/12	herniotomy	40	80	102	101	99	98	96	94	96	91	92	90	80	79	82	86	91	94	88	110	90	92	96	94	100	97	98	99	98	94	97	100	107	103	97	99	95
25	daniel	4	m	15	2311/12	circumcision	40	95	118	112	105	107	102	101	99	98	97	95	91	95	96	90	94	97	93	108	90	96	98	99	100	104	102	101	99	98	93	94	94	95	100	101	103
26	saranya	4	f	13	2319/12	herniotomy	35	90	119	114	112	110	106	102	101	98		95	88	86	85	84	86	87	88	116	90	94	95	99	100	90	92	90		96	100	102	99	95	89	99	92
27	goutham	5.5	m	20	2365/12	circumcision	30	86	102	98	96	94	92	90	89			89	90	91	92	86	86	90	92	122	110	124	120	115	114	102	101			95	104	107	105	101	99	97	95
28	ajith	8	m	18	2379/12	hydrocele	25	90	115	114	112	108	105	102				100	93	90	89	85	88	91	96	125	100	112	114	108	96	95				98	106	102	108	110	108	104	107
29	robert	7	m	16	2377/12	herniotomy	30	85	102	101	99	95	94	90	89			88	86	84	88	86	80	82	86	118	100	112	108	106	102	100	96			98	110	96	68	103	95	104	102
30	kamalesh	6	m	15	2381/12	circumcision	25	90	107	105	104	107	103	102				99	86	91	92	85	82	80	76	162	96	102	104	108	110	108				104	101	104	95	96	99	102	102

SL NO	DIASTOLIC BP																		MAP																		SpO2																	
	PERIOP										POSTOP								PERIOP										POSTOP								PERIOP										POSTOP							
	BI	AI	5'	10'	15'	20'	25'	30'	35'	40'	0'	2h	4h	8h	12h	16h	20h	24h	BI	AI	5'	10'	15'	20'	25'	30'	35'	40'	0'	2h	4h	8h	12h	16h	20h	24h	BI	AI	5'	10'	15'	20'	25'	30'	35'	40'	0'	2h	6h	8h	12h	16h	20h	24h
1	49	47	52	55	49	42	44				48	44	53	51	47	46	50	48	61	62	64	65	63	56	59				61	58	64	63	60	61	64	62	99	99	99	99	99	99	99				99	99	99	99	99	99	99	99
2	64	68	54	55	62	60	58	59	61		66	59	54	55	60	62	66	63	76	81	67	69	75	73	70	71	73		76	70	69	71	75	77	78	76	99	99	99	99	99	99	98	99	99		99	99	99	99	99	99	99	99
3	66	55	52	50	56	59					60	61	63	55	61	64	68	62	80	70	65	65	69	72	0	0	0	0	73	73	72	69	74	77	79	76	99	99	99	99	99	99					99	99	99	99	99	99	99	99
4	70	67	71	64	66	61	63	69	70		67	53	57	67	69	70	71	68	87	80	81	75	75	72	74	79	80	33	79	67	68	77	79	77	79	82	99	99	99	99	99	99	98	99	99	99	99	99	99	99	99	99	99	99
5	46	48	44	40	44	46	50				47	47	44	48	47	44	43	49	57	57	55	56	57	57	60	0	0	0	58	58	57	60	58	59	57	60	99	99	99	99	99	99	99				99	99	99	98	99	99	99	99
6	55	60	58	56	48	49	54	57			49	48	50	50	46	44	42	48	64	68	66	67	62	61	63	66	0	0	59	58	59	59	58	57	55	59	99	99	99	99	99	99	99	99			98	99	99	99	99	99	99	99
7	55	60	48	46	48	51					44	50	51	47	48	49	46	52	66	68	61	61	62	61	0	0	0	0	59	61	62	60	58	59	58	61	99	99	99	99	99	99					99	99	99	99	99	98	99	99
8	70	56	58	53	52	58	45	48	49	50	44	47	49	44	48	52	53	56	79	64	65	64	62	65	58	59	62	63	57	62	64	63	64	66	65	66	99	99	99	99	99	99	99	98	98	99	99	99	99	99	99	99	99
9	65	59	64	70	71	68	64	69			59	62	67	70	56	59	60	67	81	77	81	83	85	82	77	79	0	0	72	76	80	83	75	75	75	80	99	99	99	99	99	99	98	99			99	99	99	99	99	99	99	99
10	55	51	52	53	57	45	48				52	57	56	54	55	57	58	59	67	66	65	65	68	58	62	0	0	0	63	68	69	69	68	69	69	71	99	99	99	99	99	99	99	99	99		99	99	99	99	99	99	99	99
11	55	56	50	51	56						51	45	55	54	47	49	54	55	68	67	63	64	69	0	0	0	0	0	65	61	69	69	62	64	67	66	99	99	99	99	99						99	99	99	99	99	99	99	99
12	56	49	54	53	55	58	61	63			51	61	57	55	45	49	51	53	67	59	67	66	64	67	71	74	0	0	64	71	69	69	61	63	63	68	99	99	99	99	99	99	99	99			99	99	99	99	99	99	99	99
13	56	58	59	70	64	64	61	66	63	61	56	60	57	59	52	51	50	50	71	73	71	79	74	75	72	76	73	73	68	71	68	70	67	67	65	65	99	99	99	99	99	99	99	99	98	99	99	99	98	97	99	99	99	99
14	46	48	47	44	42	47	45				47	56	47	43	49	47	48	48	60	60	60	58	56	60	58	0	0	0	60	66	60	58	62	60	60	61	99	99	99	99	99	98	99				99	99	99	99	99	99	99	99
15	49	51	57	56	59	60	54	55	53		48	57	54	55	56	63	62	64	73	76	74	72	75	75	72	71	70	0	65	69	69	70	71	79	73	74	99	99	99	99	99	99	99	99	99		99	99	99	99	99	99	99	99
16	64	66	56	59	68	62	57	59			47	56	58	59	57	53	58	67	78	81	77	75	80	75	71	71	0	0	63	74	71	76	73	70	73	79	99	99	99	99	99	99	99	99			99	99	99	99	99	99	99	99
17	55	54	51	53	52	58	60	61	62		59	68	58	57	58	54	60	61	68	68	64	65	63	68	70	69	70	0	69	76	70	70	69	66	71	70	99	99	99	99	99	99	99	99	99		99	98	99	99	99	98	99	99
18	49	51	52	55	56	57	58	59	61	64	61	57	59	61	62	64	65	59	65	71	71	72	72	72	73	74	76	77	75	70	72	73	75	76	76	72	99	99	99	99	99	98	99	99	99	99	99	99	99	99	99	99	99	99
19	55	56	54	49	48	44	47				54	61	62	59	60	63	57	55	67	66	65	63	63	61	64	0	0	0	69	73	73	73	73	75	70	68	99	99	99	99	99	99	99				99	99	99	99	98	99	99	99
20	56	68	60	59	58	54	57				49	61	65	57	59	61	65	64	70	79	72	71	71	67	70	0	0	0	66	76	79	72	72	73	75	75	99	99	99	99	99	99	99				99	99	99	99	99	99	99	99
21	65	67	64	67	58	57	59	60			52	51	52	57	59	60	58	57	80	77	75	78	59	70	72	73	0	0	66	67	68	73	71	72	71	69	99	99	99	99	99	99	99	99			98	99	99	99	99	99	99	99
22	64	62	61	62	59	58	57	61	62		67	71	71	68	64	65	69	58	81	73	74	75	72	72	72	73	74	0	77	80	79	80	76	75	78	71	99	99	99	99	99	99	98	99	99		99	99	99	99	99	99	99	99
23	64	64	63	67	70	71	69	68	62		56	61	67	59	64	63	62	67	81	76	74	77	80	83	81	79	76	0	69	74	79	76	77	74	74	77	99	99	99	99	99	99	99	99	99		99	99	99	99	99	99	99	99
24	67	64	65	63	62	58	54	47	49	58	57	55	56	58	64	67	66	62	81	73	74	74	73	72	68	64	66	71	69	69	71	74	77	77	77	73	99	99	99	99	99	99	98	98	98	99	99	99	99	99	99	99	99	99
25	65	62	61	54	55	57	56	57	59	61	57	55	53	54	51	58	60	54	79	71	73	69	70	71	72	72	73	74	71	68	67	67	66	72	74	70	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99
26	55	52	56	61	63	64	68	55	56		55	61	59	54	56	58	59	57	75	65	69	72	75	76	75	67	67	0	69	74	73	69	69	68	72	69	99	99	99	99	99	99	99	99	99		99	99	99	99	99	99	99	99
27	64	60	56	64	67	52	49	52			55	72	65	66	62	68	66	64	83	77	79	83	83	73	67	68	0	0	68	83	79	79	75	78	76	74	99	99	99	99	99	99	99	99			99	99	99	99	99	99	99	99
28	65	66	64	62	56	58	59				56	58	89	60	64	65	53	54	85	77	80	79	73	71	71	0	0	0	70	74	93	76	79	79	70	72	99	99	99	99	99	99	99				99	99	99	98	99	99	99	99
29	65	67	68	56	58	59	63	65			62	62	57	50	49	52	23	59	83	78	83	73	74	73	75	75	0	0	74	78	70	56	67	66	50	73	99	99	99	99	99	99	99	99			99	99	99	99	99	99	99	99
30	65	56	54	58	59	54	58				61	54	49	48	52	55	57	68	97	69	70	73	75	73	75	0	0	0	75	70	67	64	67	70	72	79	99	99	99	99	99	99	99				99	99	99	99	99	99	99	99

GROUP-B																
SL NO	PAIN SCORE(FLACC) POSTOP					DURATION OF ANALGESIA	sedation score								PONV	RTN OF URINE
	0	2h	4h	6h	8h		30	60	1.5h	2h	3h	4h	5h	6h		
1	0	0	3	4		315	3	2	3	1					NIL	NIL
2	0	0	3	4		325	3	3	2	2	1				NIL	NIL
3	0	0	2	4		330	3	3	2	2	2	1			NIL	NIL
4	0	0	3	4		300	3	3	2	2	2	2	1		NIL	NIL
5	0	0	4			260	3	3	2	2	1	2	2	1	NIL	NIL
6	0	0	2	4		315	3	3	3	2	2	2	2	1	NIL	NIL
7	0	0	3	4		335	3	3	2	2	1				NIL	NIL
8	0	0	4			260	3	3	3	2	2	2	1		NIL	NIL
9	0	0	4			250	3	3	3	2	2	1			NIL	NIL
10	0	0	1	4		315	3	3	2	2	2	1			NIL	NIL
11	0	0	3	4		330	3	3	3	2	2	1			NIL	NIL
12	0	0	3	4		340	3	3	3	2	2	1			NIL	NIL
13	0	0	2	4		320	3	3	2	2	2	1			NIL	NIL
14	0	0	4			280	3	3	2	2	2	1			NIL	NIL
15	0	0	2	4		310	3	2	2	2	2	2			NIL	NIL
16	0	0	3	4		325	3	3	2	2	2	1			NIL	NIL
17	0	0	3	4		310	3	3	3	2	2	2	1		NIL	NIL
18	0	0	1	4		335	3	3	3	2	2	1	2		NIL	NIL
19	0	0	2	4		310	3	3	3	2	2	2	2		NIL	NIL
20	0	0	3	4		340	3	3	3	2	2	1			NIL	NIL
21	0	0	2	4		320	3	3	3	2	1				NIL	NIL
22	0	0	4			260	3	3	3	2	1				NIL	NIL
23	0	0	2	4		340	3	3	3	2	1				NIL	NIL
24	0	0	1	4		310	3	3	2	2	1				NIL	NIL
25	0	0	4			220	3	3	3	2	1				NIL	NIL
26	0	0	2	4		280	3	3	3	2	2	1			NIL	NIL
27	0	0	2	4		305	3	2	2	2	1				NIL	NIL
28	0	0	3	4		315	3	2	2	2	2	2	1		NIL	NIL
29	0	0	1	3	4	360	3	3	3	2	2	2	2	1	NIL	NIL
30	0	2	3	4		305	3	3	2	2	2	2	1		NIL	NIL

GROUP - BD		MASTER CHART						HEART RATE																						SYSTOLIC BP																	
SL NO	NAME	AGE	SEX	WT	IP NO	SURGERY	DOS	PERIOP												POSTOP								PERIOP												POSTOP							
								BI	AI	5'	10'	15'	20'	25'	30'	35'	40'	45'	50'	0'	2h	4h	8h	12h	16h	20h	24h	BI	AI	5'	10'	15'	20'	25'	30'	35'	40'	50'	0'	2h	4h	8h	12h	16h	20h	24h
1	sivakumar	5	m	15	2388/12	herniotomy	35	90	109	105	100	98	95	90	98	94				90	70	80	84	86	88	90	91	114	90	91	88	92	94	88	90	98			90	97	92	101	96	94	95	99
2	sabarish	2	m	10	2392/12	circumcision	30	100	135	130	126	124	114	108	102					95	70	76	88	92	94	96	97	80	72	75	78	81	82	80	85				80	91	92	94	88	86	82	86
3	kalaibarathi	1.5	f	8	2398/12	herniotomy	40	102	133	133	124	114	108	104	100	96	99			90	92	88	91	93	94	97	99	80	76	82	78	76	78	80	82	86	84		80	85	79	84	80	79	78	81
4	aarthi	5	f	20	2400/12	hydrocele	30	86	125	122	116	108	102	101	98					95	83	91	92	94	93	90	97	116	94	100	102	104	105	105	100	98	102		102	96	94	96	98	100	108	102
5	kishore	1	m	10	2412/12	circumcision	35	111	132	126	122	118	108	105	107	104				99	83	79	86	88	9	94	98	76	74	80	82	86	85	84	79	82			79	80	82	81	80	79	78	79
6	kamalesh	6	m	15	2415/12	herniotomy	40	89	104	101	99	97	96	92	88	86	89			88	84	82	90	92	91	96	95	125	100	96	92	94	98	96	98	99	97		95	100	112	98	96	97	102	105
7	anandh	7	m	22	2417/12	hydrocele	30	86	114	108	104	98	96	92	90					88	92	90	96	94	97	99	95	126	102	103	100	96	94	98	102				98	105	98	102	95	96	98	96
8	kalidas	4	m	12	2418/12	circumcision	35	98	130	128	122	120	109	100	98					96	88	86	92	93	96	94	94	126	122	108	106	104	100	98	102	104			108	105	104	110	108	102	98	96
9	rahul	4	m	16	2467/12	herniotomy	40	95	126	120	109	105	102	105	106	107	99			98	91	92	94	94	96	97	94	100	90	86	92	95	92	90	89	96	98		98	106	100	96	108	114	116	112
10	nazir	2	m	12	2430/12	orchidopexy	40	98	126	122	118	108	105	103	100	98	96			95	88	86	95	92	94	92	98	85	84	82	80	76	78	78	81	83	85		88	85	86	90	94	96	88	95
11	bharath	5	m	17	2439/12	circumcision	30	96	118	115	114	110	108	104	100					96	88	91	98	95	99	92	94	91	92	95	100	95	98	97	96				94	103	102	103	114	112	113	108
12	tharunmani	4	m	15	2455/12	hydrocele	30	99	126	122	109	105	104	99	95					95	91	93	95	94	91	93	95	102	103	105	110	118	106	106	108				100	108	104	110	105	104	103	101
13	sarath	3	m	14	2459/12	herniotomy	30	102	126	122	114	110	105	102	98					96	86	84	87	86	85	91	92	98	90	88	95	96	100	104	97				98	89	100	102	98	95	98	99
14	joshva	1	m	8	2471/12	circumcision	25	106	135	125	120	114	114	108						104	86	88	92	94	95	91	90	78	79	80	82	85	78	79					80	80	79	72	76	81	83	80
15	ferhose	3.5	m	10	2481/12	hydrocele	30	101	128	124	116	108	104	101	99					96	78	85	82	80	78	76	78	114	100	98	96	94	92	98	104				96	96	92	90	93	100	96	95
16	manikandan	6	m	16	2491/12	orchidopexy	40	88	108	106	104	102	101	95	95	96	92			87	74	82	84	88	82	86	88	124	100	102	104	113	108	102	100	98	105		98	101	105	108	100	98	95	99
17	kannan	6	m	15	2503/12	herniotomy	30	90	117	108	106	102	98	95	97					95	88	80	86	89	91	92	89	100	96	98	102	104	98	96	97				98	105	100	98	96	101	108	110
18	sunil	4	m	14	2509/12	circumcision	30	110	126	125	115	108	100	98	96					94	92	85	92	94	93	88	91	110	92	96	98	97	105	106					98	97	103	107	110	98	95	96
19	ramkumar	7	m	18	2522/12	hydrocele	35	98	118	108	106	104	102	100	96					94	88	86	81	80	79	78	81	124	110	106	102	100	98	96	99	101			112	106	103	98	107	109	108	110
20	prashanth	2	m	10	2529/12	orchidopexy	50	110	132	128	126	120	114	104	102	108	102	98	98	96	84	82	86	97	91	95	94	86	80	82	81	83	82	85	81	86	84	82	83	83	87	85	86	91	93	95
21	mohanraj	5	m	14	2535/12	circumcision	25	100	116	96	94	92	91	96						91	86	87	91	90	92	93	96	110	106	98	103	104	105	100					96	94	97	92	99	94	96	94
22	vimal	2	m	9	2539/12	circumcision	25	102	119	118	116	110	110	108						104	86	91	94	96	97	92	97	92	84	86	84	84	82	86					86	85	88	87	86	88	92	93
23	sarath	6	m	16	2542/12	herniotomy	35	99	128	124	118	114	108	102	104	101				101	84	78	83	82	80	88	91	121	108	105	102	100	102	108	112	116			108	102	105	107	98	103	105	112
24	vignesh	5	m	15	2547/12	hydrocele	30	95	114	112	110	106	104	100	98					96	88	84	82	83	91	95	92	116	112	108	112	96	92	96	99				96	97	105	112	101	104	99	107
25	vetri	7	m	17	2544/12	herniotomy	35	90	119	115	112	108	104	103	100	98				96	88	86	91	95	92	91	89	126	114	108	102	99	96	94	102	108			104	108	103	105	106	108	114	109
26	silambu	3	m	12	2564/12	circumcision	30	98	121	116	112	108	104	102	98					96	88	86	91	88	86	88	87	91	93	95	85	91	88	93	90				92	94	95	98	102	106	103	106
27	karthiga	4	f	15	2567/12	herniotomy	40	92	115	112	108	104	102	100	98	96	99			96	88	86	91	93	92	91	90	108	112	102	96	92	90	95	96	102	106		102	104	101	96	98	99	103	104
28	siddharth	2	m	10	2567/12	circumcision	30	106	135	132	130	126	121	116	108					102	92	90	88	85	79	82	88	80	79	91	84	86	82	87	88				88	86	88	84	86	84	83	79
29	david	3	m	14	2601/12	hydrocele	35	100	123	122	118	109	105	102	101	105				100	82	80	78	81	76	82	82	96	89	91	88	87	91	94	94	97			94	96	98	97	100	103	105	107
30	alagu	2.5	m	10	2615/12	herniotomy	30	108	132	131	126	122	118	114	112					108	95	86	78	80	88	92	96	94	89	88	86	84	82	87	86				93	93	89	95	91	93	92	98

group-BD

SL NO	DIASTOLIC BP																	
	PERIOP										POSTOP							
	BI	AI	5'	10'	15'	20'	25'	30'	35'	40'	0'	2h	4h	8h	12h	16h	20h	24h
1	65	48	44	47	48	57	55	52	60		58	53	61	65	66	69	62	60
2	46	47	42	51	51	50	57	50			44	44	47	42	44	47	47	51
3	46	48	47	45	49	46	44	42	47	45	42	50	49	47	45	44	46	49
4	64	60	56	58	57	58	59	62			58	61	63	64	58	57	54	56
5	46	45	47	44	47	46	44	48	46		45	53	49	48	46	47	48	51
6	55	56	58	57	49	51	54	58	61	65	56	58	59	61	63	67	68	66
7	56	56	61	60	67	62	64	66			60	58	59	61	60	64	62	60
8	56	58	61	64	63	65	66	67	70		56	63	56	59	57	58	62	60
9	61	62	58	56	54	55	58	59	62	64	58	58	54	54	57	55	52	58
10	56	58	60	62	63	64	62	59	58	57	46	51	49	48	50	52	55	54
11	56	58	54	55	61	59	63	67			58	51	52	53	52	55	51	49
12	56	52	52	51	49	52	56	55			55	51	55	59	57	52	57	59
13	54	52	49	48	50	56	62	61			54	58	51	50	54	55	56	57
14	45	48	44	51	53	47	44				49	51	52	50	47	48	45	44
15	51	53	55	49	48	47	51	56			51	46	44	50	53	58	46	43
16	54	50	58	57	66	64	63	62	59	58	54	62	60	67	64	63	62	64
17	64	62	56	55	58	56	49	57			67	52	49	52	54	56	57	58
18	67	60	58	54	55	56	57	58			55	53	64	66	60	46	52	55
19	66	62	56	58	2	60	66	70	64		54	56	48	47	54	52	56	54
20	46	47	48	51	53	55	52	51	45	47	51	47	49	48	51	53	50	52
21	46	48	51	53	54	55	57				54	57	53	58	63	62	55	54
22	46	47	48	51	53	52	54				55	58	45	48	50	53	55	57
23	55	56	58	61	62	67	58	62	66		55	61	66	67	49	48	51	53
24	56	58	61	63	64	66	59	65			57	58	57	61	63	66	65	59
25	66	67	63	59	58	56	57	52	54		56	68	64	62	60	54	58	56
26	56	58	54	57	61	60	52	48			49	61	60	59	54	52	51	58
27	56	52	48	49	52	55	55	53	56	59	56	54	55	58	61	63	65	63
28	46	44	51	52	54	49	50	52			48	51	46	47	42	46	53	56
29	56	58	59	61	63	62	59	58	63		55	62	60	57	54	52	53	52
30	56	54	52	55	57	56	53	54			60	49	46	47	43	44	51	50

SL NO	MAP																	
	PERIOP										POSTOP							
	BI	AI	5'	10'	15'	20'	25'	30'	35'	40'	0'	2h	4h	8h	12h	16h	20h	24h
1	81	62	60	61	63	69	66	65	73		69	67.7	71.3	77	76	77.3	73	73
2	57	55	53	60	61	61	65	62			56	59.7	62	59.3	58.7	60	58.7	62.7
3	57	57	59	56	58	57	56	55	60	58	55	61.7	59	59.3	56.7	55.7	56.7	59.7
4	81	71	71	73	73	74	74	75	33	34	73	72.7	73.3	74.7	71.3	71.3	72	71.3
5	56	55	58	57	60	59	57	58	58		56	62	60	59	57.3	57.7	58	60.3
6	78	71	71	69	64	67	68	71	74	76	69	72	76.7	73.3	74	77	79.3	79
7	79	71	75	73	77	73	75	78			73	73.7	72	74.7	71.7	74.7	74	72
8	79	79	77	78	77	77	77	79	81		73	77	72	76	74	72.7	74	72
9	74	71	67	68	68	67	69	69	73	75	71	74	69.3	68	74	74.7	73.3	76
10	66	67	67	68	67	69	67	66	66	66	60	62.3	61.3	62	64.7	66.7	66	67.7
11	68	69	68	70	72	72	74	77			70	68.3	68.7	69.7	72.7	74	71.7	68.7
12	71	69	70	71	72	70	73	73			70	70	71.3	76	73	69.3	72.3	73
13	69	65	62	64	65	71	76	73			69	68.3	67.3	67.3	68.7	68.3	70	71
14	56	58	56	61	64	57	56				59	60.7	61	57.3	56.7	59	57.7	56
15	72	69	69	65	63	62	67	72			66	62.7	60	63.3	66.3	72	62.7	60.3
16	77	67	73	73	82	79	76	75	72	74	69	75	75	80.7	76	74.7	73	75.7
17	76	73	70	71	73	70	65	70			77	69.7	66	67.3	68	71	74	75.3
18	81	71	71	69	69	72	73	39			69	67.7	77	79.7	76.7	63.3	66.3	68.7
19	85	78	73	73	35	73	76	80	76		73	72.7	66.3	64	71.7	71	73.3	72.7
20	59	58	59	61	63	64	63	61	59	59	62	59	61.7	60.3	62.7	65.7	64.3	66.3
21	67	67	67	70	71	72	71				68	69.3	67.7	69.3	75	72.7	68.7	67.3
22	61	59	61	62	63	62	65				65	67	59.3	61	62	64.7	67.3	69
23	77	73	74	75	75	79	75	79	83		73	74.7	79	80.3	65.3	66.3	69	72.7
24	76	76	77	79	75	75	71	76			70	71	73	78	75.7	78.7	76.3	75
25	86	83	78	73	72	69	69	69	72		72	81.3	77	76.3	75.3	72	76.7	73.7
26	68	70	68	66	71	69	66	62			63	72	71.7	72	70	70	68.3	74
27	73	72	66	65	65	67	68	67	71	75	71	70.7	70.3	70.7	73.3	75	77.7	76.7
28	57	56	64	63	65	60	62	64			61	62.7	60	59.3	56.7	58.7	63	63.7
29	69	68	70	70	71	72	71	70	74		68	73.3	72.7	70.3	69.3	69	70.3	70.3
30	69	66	64	65	66	65	64	65			71	63.7	60.3	63	59	60.3	64.7	66

SL NO	SpO2																	
	PERIOP										POSTOP							
	BI	AI	5'	10'	15'	20'	25'	30'	35'	40'	0'	2h	6h	8h	12h	16h	20h	24h
1	99	99	99	99	99	99	99	99	99		99	99	99	99	99	99	99	99
2	99	99	99	99	99	99	99	99			99	99	99	99	99	99	99	99
3	99	99	99	99	99	99	99	98	98	99	99	99	99	99	99	99	99	99
4	99	99	99	99	99	99	99	99	98	99	99	99	99	99	99	99	99	99
5	99	99	99	99	99	99	98	99	99		99	99	99	99	99	99	99	99
6	99	99	99	99	99	99	99	99	99	98	99	99	99	99	99	99	99	99
7	99	99	99	99	99	99	99	99			99	99	99	99	99	99	99	99
8	99	99	99	99	99	99	99	99	99		99	99	99	99	99	99	99	99
9	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99
10	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99
11	99	99	99	99	99	99	99	99			99	99	99	99	99	99	99	99
12	99	99	99	99	99	99	99	99			99	99	99	99	99	99	99	99
13	99	99	99	99	99	99	99	99			99	99	99	99	99	99	99	99
14	99	99	99	99	99	99	99				99	99	99	99	99	99	99	99
15	99	99	99	99	99	99	99	99			99	99	99	99	99	99	99	99
16	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99
17	99	99	99	99	99	99	99	99			99	99	99	99	99	99	99	99
18	99	99	99	99	99	99	99	99			99	99	99	99	99	99	99	99
19	99	99	99	99	99	99	99	99	99		99	99	99	99	99	99	99	99
20	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99
21	99	99	99	99	99	99	99				99	99	99	99	99	99	99	99
22	99	99	99	99	99	99	99				99	99	99	99	99	99	99	99
23	99	99	99	99	99	99	99	99	99		99	99	99	99	99	99	99	99
24	99	99	99	99	99	99	99	99			99	99	99	99	99	99	99	99
25	99	99	99	99	99	99	99	99	99		99	99	99	99	99	99	99	99
26	99	99	99	99	99	99	99	99			99	99	99	99	99	99	99	99
27	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99	99
28	99	99	99	99	99	99	99	99			99	99	99	99	99	99	99	99
29	99	99	99	99	99	99	99	99	99		99	99	99	99	99	99	99	99
30	99	99	99	99	99	99	99	99			99	99	99	99	99	99	99	99

SL NO	PAIN SCORE(FLACC) POSTOP										DURATION OF	SEDATION SCORE								PONV	RTN OF URINE
	0	2h	4h	6h	8h	10	12h	16h	20h	24h	ANALGESIA	30	60	1.5h	2h	3h	4h	5h	6h		
1	0	0	1	2	3	4					600	5	4	3	3	3	2	2	1	nil	nil
2	0	0	0	0	2	3	4				700	5	4	4	3	2	2	2	1	nil	nil
3	0	0	0	2	2	4					590	5	4	3	3	2	2	2	1	nil	nil
4	0	0	0	1	2	4					610	5	4	3	3	2	2	2	1	nil	nil
5	0	0	0	2	2	3	4				720	5	4	3	3	3	3	2	1	nil	nil
6	0	0	0	0	3	4					590	5	4	3	3	2	2	3	1	nil	nil
7	0	0	0	0	2	3	4				720	5	4	3	3	3	2	2	1	nil	nil
8	0	0	0	0	3	4					610	5	4	3	3	3	3	3	1	nil	nil
9	0	0	0	0	2	3	4				690	5	4	3	3	2	2	2	1	nil	nil
10	0	0	0	0	2	4					610	5	4	3	3	3	3	3	1	nil	nil
11	0	0	0	1	2	4					620	5	4	3	3	3	3	2	1	nil	nil
12	0	0	0	0	0	2	3	4			900	5	4	4	3	2	2	2	1	nil	nil
13	0	0	0	0	2	3	4				690	5	4	3	2	2	2	2	1	nil	nil
14	0	0	0	0	3	4					630	5	4	3	3	3	3	2	1	nil	nil
15	0	0	0	1	3	4					650	5	4	3	3	3	3	2	1	nil	nil
16	0	0	0	0	1	2	4				700	5	4	3	2	2	2	2	1	nil	nil
17	0	0	0	2	3	4					630	5	4	4	3	2	2	2	1	nil	nil
18	0	0	0	0	1	3	4				710	5	4	3	2	2	2	2	1	nil	nil
19	0	0	0	0	2	3	4				730	5	4	3	2	2	2	2	1	nil	nil
20	0	0	0	0	0	2	3	4			850	5	4	3	2	2	2	1	1	nil	nil
21	0	0	0	1	2	4					650	5	4	3	2	2	2	2	1	nil	nil
22	0	0	0	0	1	3	4				720	5	4	3	2	2	2	3	1	nil	nil
23	0	0	0	0	1	3	4				730	5	4	3	3	3	3	2	1	nil	nil
24	0	0	0	0	0	4					620	5	4	4	3	2	2	2	1	nil	nil
25	0	0	0	0	1	2	4				750	5	4	3	2	2	2	2	1	nil	nil
26	0	0	0	0	2	4					620	5	4	3	3	3	3	3	1	nil	nil
27	0	0	0	0	2	3	4				730	5	4	4	3	2	2	2	1	nil	nil
28	0	0	0	0	3	4					630	5	4	3	3	3	3	2	1	nil	nil
29	0	0	0	0	1	3	4				750	5	4	3	2	2	2	2	1	nil	nil
30	0	0	0	0	2	3	4				720	5	4	4	4	3	2	2	1	nil	nil

INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI -3

Telephone No : 044 25305301
Fax : 044 25363970

CERTIFICATE OF APPROVAL

To
Dr.N. Hariprakash
PG in M.D.Anaesthesiology
Madras Medical College & Rajiv Gandhi Govt. General Hospital,
Chennai -3

Dear Dr.N. Hariprakash,

The Institutional Ethics committee of Madras Medical College, reviewed and discussed your application for approval of the proposal entitled " Prospective randomized control study on effect of adding dexmedetomidine to caudal bupivacaine for postoperative analgesia in children" No.12112012.

The following members of Ethics Committee were present in the meeting held on 01.11.2012 conducted at Madras Medical College, Chennai -3.

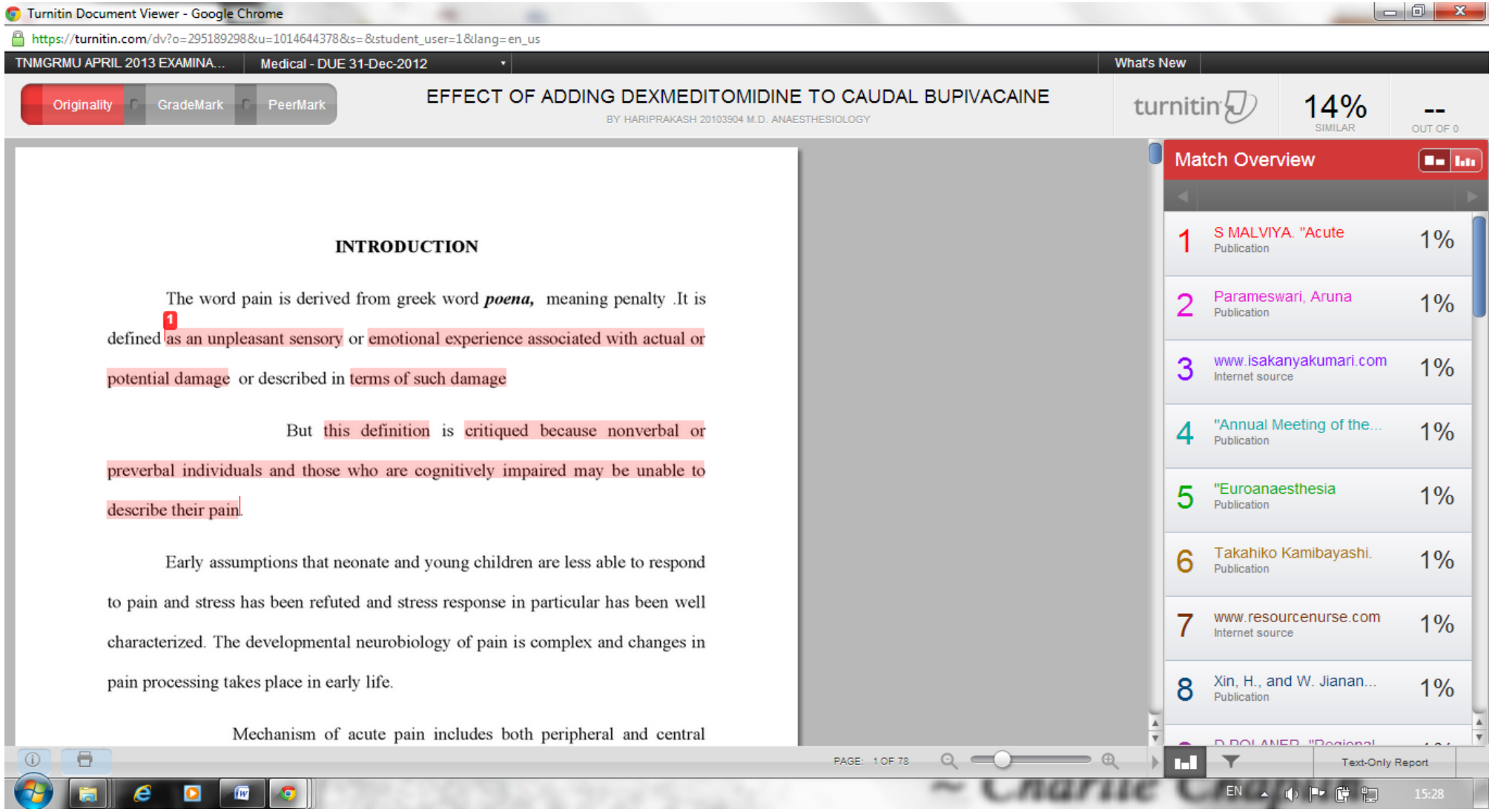
1. Prof. R. Nandhini MD -- Member Secretary
   Director, Instt. of Pharmacology ,MMC, Ch-3
2. Prof. Reghu MD -- Member
   Director , Inst. Of Internal Medicine, MMC, Ch-3
3. Prof. Shyamraj MD -- Member
   Director i/c , Instt. of Biochemistry , MMC, Ch-3
4. Prof. P. Karkuzhali. MD -- Member
   Prof., Instt. of Pathology, MMC, Ch-3
5. Prof. G.Muralidharan MS -- Member
   Prof of Surgery, MMC, Ch-3
6. Thiru. S. Govindsamy. BA, BL -- Lawyer

We approve the proposal to be conducted in its presented form.

Sd/ Chairman & Other Members

The Institutional Ethics Committee expects to be informed about the progress of the study, and SAE occurring in the course of the study, any changes in the protocol and patients information / informed consent and asks to be provided a copy of the final report.

R Nadini 19/11/12
Member Secretary, Ethics Committee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INTRODUCTION
The word pain is derived from greek word poena, meaning penalty .It is defined as an unpleasant sensory or emotional experience associated with actual or potential damage or described in terms of such damage
But this definition is critiqued because nonverbal or preverbal individuals and those who are cognitively impaired may be unable to describe their pain.
Early assumptions that neonate and young children are less able to respond to pain and stress has been refuted and stress response in particular has been well characterized. The developmental neurobiology of pain is complex and changes in pain processing takes place in early life.
Mechanism of acute pain includes both peripheral and central
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PROFORMA

Date: Roll no: Group

Name: Age/Sex: IP no:

Wt:

Diagnosis:

Surgical Procedure done:

Pre op assessment:

History:

Any H/O co-morbid illness

Any H/O previous surgery

O/E: CVS: RS:

BP: PR: SPO2:

ASA status:

Drugs used:

Induction: Maintenance:

Time of administration of caudal block:

Duration of surgery:

Intra OP events:

Time	Events	HR	BP	SPO2

Post OP events

Time(Hrs)	HR	BP	Pain Score	Sedation Score

Complication:

Group	Respiratory Depression	Apnea	Pruitis	Urinary Retention	Nausea & Vomiting

DOSE TIME

Inj.ATROPINE

Inj.EPHEDRINE

PATIENT CONSENT FORM

Study title : **"Effect of Dexmeditomidine with Bupivacaine for Caudal Block in Lower Abdominal Surgeries in Children "**

Study centre : Institute of Child health &Hospital for children
Madras medical college, Chennai.

Participant name : Age: Sex: I.P.No:

I confirm that i have understood the purpose of procedure for the above study. i have the opportunity to ask the question and all my questions and doubts have been answered to my satisfaction.

I have been explained about the pitfall in the procedure. I have been explained about the safety, advantage and disadvantage of the technique.

I understand that my Child participation in the study is voluntary and that i am free to withdraw at anytime without giving any reason.

I understand that investigator, regulatory authorities and the ethics committee will not need my permission to look at my Child health records both in respect to current study and any further research that may be conducted in relation to it, even if i withdraw from the study. I understand that my child identity will not be revealed in any information released to third parties or published, unless as required under the law. I agree not to restrict the use of any data or results that arise from the study.

Time:

Date: signature / thumb impression of parent

Place: parent name:

Signature of the investigator:

Name of the investigator: